Federal Register

Friday,

August 24, 2001

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 413, et al.

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2002 Payment Rates; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 419, and 489

[CMS–1159–P]

RIN 0938–AK54

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2002 Payment Rates

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 and changes arising from our continuing experience with this system. In addition, it would describe proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2002.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 3, 2001.

ADDRESSES: In commenting, please refer to file code CMS–1159–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1159–P, P.O. Box 8017, Baltimore, MD 21244–8017.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivery.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received too late for us to consider them.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

When ordering copies of the **Federal Register** containing this document, see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: George Morey (410) 786–4653, for provider-based issues; and Nancy Edwards (410) 786–0378, for all other issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21244–1850 on Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call (410) 786–7195 or (410) 786–4668.

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Outline of Contents

Alphabetical List of Acronyms Appearing in the Proposed Rule

APC Ambulatory payment classification
APG Ambulatory patient group
ASC Ambulatory surgical center
AWP Average wholesale price
BBA 1997 Balanced Budget Act of 1997
BIPA 2000 Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
BBRA 1999 Balanced Budget Refinement Act of 1999
CAH Critical access hospital
CAT Computerized axial tomography
CCI Correct Coding Initiative
CCR Cost center specific cost-to-charge ratio
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services (Formerly known as the Health Care Financing Administration)
CORF Comprehensive outpatient rehabilitation facility
CPI Consumer Price Index
CPT (Physician's) Current Procedural Terminology, Fourth Edition, 2001, copyrighted by the American Medical Association
DME Durable medical equipment
DMEPOS DME, prosthetics (which include prosthetic devices and implants) orthotics, and supplies
DRG Diagnosis-related group
EMTALA Emergency Medical Treatment and Active Labor Act
FDA Food and Drug Administration
FQHC Federally qualified health center
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
ICD–9–CM International Classification of Diseases, Ninth Edition, Clinical Modification
IME Indirect medical education
JCAHO Joint Commission on Accreditation of Healthcare Organizations
MRI Magnetic resonance imaging
MSA Metropolitan statistical area
NECMA New England County Metropolitan Area
OPPS Hospital outpatient prospective payment system
PPS Prospective payment system
RFA Regulatory Flexibility Act
RHC Rural health clinic
RRC Rural referral center
SCH Sole community hospital
SNF Skilled nursing facility

I. Background

A. Authority

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted on December 21, 2000, made further changes in the OPPS. The BIPA provisions that affect the OPPS are summarized below, in section I.C. The OPPS was first implemented for services furnished on or after August 1, 2000.

B. Summary of Rulemaking

- On September 8, 1998, we published a proposed rule (63 FR 47552) to establish in regulations a PPS for hospital outpatient services, to eliminate the formula-driven overpayment for certain hospital outpatient services, and to extend reductions in payment for costs of hospital outpatient services. On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographic errors in the September 1998 proposed rule including the proposed amounts and factors used to determine the payment rates.
- On April 7, 2000, we published a final rule with comment period (65 FR 18438) that addressed the provisions of the PPS for hospital outpatient services scheduled to be effective for services furnished on or after July 1, 2000. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. These outpatient services are classified according to a list of ambulatory payment classifications (APCs). The April 7 final rule with comment period also established requirements for provider departments and provider-based entities and prohibited Medicare payment for non-physician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under arrangement. In addition, this rule extended reductions in payment for costs of hospital outpatient services as required by the BBA of 1997 and

amended by the BBRA of 1999. Medicare regulations governing the hospital OPPS are set forth at 42 CFR 419.

- On June 30, 2000, we published a notice (65 FR 40535) announcing a delay in implementation of the OPPS from July 1, 2000 to August 1, 2000.
- On August 3, 2000, we published an interim final rule with comment period (65 FR 47670) that modified criteria that we use to determine which medical devices are eligible for transitional pass-through payments. The August 3, 2000 rule also corrected and clarified certain provider-based provisions included in the April 7, 2000 rule.
- On November 13, 2000, we published an interim final rule with comment period (65 FR 67798). This rule provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. We also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.

C. Summary of Relevant Provisions of the BIPA

The BIPA, which was enacted on December 21, 2000, made the following changes to the Act relating to OPPS.

1. Accelerated Reduction of Beneficiary Copayment

Section 111 amended section 1833(t)(8)(C) of the Act to limit the national copayment rate for OPPS services to 57 percent of the OPPS payment rate for services furnished in 2001 on or after April 1, 2001; 55 percent for services in 2002 and 2003; 50 percent for services furnished in 2004; 45 percent for services furnished in 2005; and 40 percent for services furnished in 2006 and thereafter.

Section 111 also specifies that nothing in BIPA 2000 or the Act, shall be viewed as preventing a hospital from waiving the amount of any beneficiary coinsurance for outpatient hospital services that may have been increased as a result of implementation of the OPPS.

2. Revision of Payment Update

Section 401 amended section 1833(t)(3)(C) of the Act to provide in 2001 an update equal to the full rate of increase in the market basket index. The 2002 update factor remains as it was under the law before the enactment of BIPA, that is, the market basket index percentage increase minus 1 percentage point.

3. Process and Standards for Determining Eligibility of Devices for Transitional Pass-Through Payments

Section 402 amended section 1833(t)(6) of the Act to require that the determination of eligibility for transitional pass-through payments be based on categories of devices (previously, eligibility was determined on a device-specific basis). The establishment of an initial set of categories was required effective for services furnished on or after April 1, 2001. This provision was implemented on March 22, 2001 in Program Memorandum (PM) No. A–01–41, which set forth a list of 96 initial categories.

Section 402 of the BIPA also provides that the Secretary must establish criteria to use in creating additional device categories. These criteria will be set forth in an interim final rule with comment period that will be published in the **Federal Register** at a later date.

Related to this issue is the issue of pro rata reductions of transitional pass through payments for new technology. A discussion of this can be found later in this document in Section VII. B.

4. Application of Transitional Corridor Payments to Certain Hospitals That Did Not Submit a 1996 Cost Report

Section 403 amended section 1833(t)(7)(F)(ii)(I) of the Act to allow transitional corridor payments to hospitals subject to the OPPS that did not have a 1996 cost report by authorizing the use of the first available cost reporting period ending after 1996 and before 2001.

5. Treatment of Children's Hospitals

Section 405 amended section 1833(t) of the Act to give children's hospitals the same permanent hold harmless protection as cancer hospitals under the OPPS.

6. Transitional Pass-Through Payment for Temperature Monitored Cryoablation

Section 406 amended section 1833(t)(6)(A)(ii) of the Act to include devices of temperature monitored cryoablation as eligible for transitional pass-through payments. This provision will be included in the interim final rule concerning changes in eligibility of devices for transitional pass-through payments mentioned above.

7. Contrast Enhanced Diagnostic Procedures

Section 430 amended section 1833(t)(2) of the Act to require that procedures that use contrast agents be classified in groups that are separate from those to which procedures not using contrast agents are assigned. We implemented this provision in PM No. A–01–73, issued on June 1, 2001. In addition, section 430 amended section 1861(t)(1) of the Act to expand the definition of drugs to include contrast agents effective for contrast agents furnished on or after July 1, 2001.

8. Other Changes

In addition to the provisions directly related to OPPS, BIPA included the following provisions that will require revision in the services assigned to APCs in the OPPS:

- Section 102 amended section 1861(s)(2) of the Act to allow coverage of glaucoma screening for certain high risk individuals effective for services furnished on or after January 1, 2002.
- Section 104(d)(2) directed the Secretary to determine if HCPCS codes are appropriate to describe mammography that uses new technology. The Secretary has created these codes for 2002.

Throughout this proposed rule, we discuss these various provisions and the changes we are proposing to make in the OPPS for them.

II. Proposed Changes to the APC Groups and Relative Weights

Under the OPPS, we pay for hospital outpatient services on a rate per service basis that varies according to the APC group to which the service is assigned. Each APC weight represents the median hospital cost of the services included in that APC relative to the median hospital cost of the services included in APC 0601, Mid-Level Clinic Visits. As described in the April 7, 2000 final rule (65 FR 18484), the APC weights are scaled to APC 0601 because a mid-level clinic visit is one of the most frequently performed services in the outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review the components of the OPPS not less often than annually and to revise the groups and related payment adjustment factors to take into account changes in medical practice, changes in technology, and the addition of the new services, new cost data, and other relevant information. Section 1833(t)(9)(A) of the Act requires the Secretary, beginning in 2001, to consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights.

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to

the use of resources if the highest median or mean cost item or service in the group is more than 2 times greater than the lowest median or mean cost item or service within the same group (referred to as the ''2 times rule''). We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule ''in unusual cases, such as low volume items and services.''

The APC groups that we are proposing in this rule as the basis for payment in 2002 under the OPPS have been analyzed within this statutory framework.

A. Recommendations of the Advisory Panel on APC Groups

1. Establishment of the Advisory Panel

Section 1833(t)(9)(A) of the Act, which requires that we consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights, specifies that the panel will act in an advisory capacity. The expert panel, which is to be composed of representatives of providers, is to review and advise us about the clinical integrity of the APC groups and their weights. The panel is not restricted to using our data and may use data collected or developed by organizations outside the Department in conducting its review.

On November 21, 2000, the Secretary signed the charter establishing an ''Advisory Panel on APC Groups'' (the Panel). The Panel is technical in nature and is governed by the provisions of the Federal Advisory Committee Act (FACA) as amended (Public Law 92–463). To establish the Panel, we solicited members in a notice published in the **Federal Register** on December 5, 2000 (65 FR 75943). We received applications from more than 115 individuals nominating either themselves or a colleague. After carefully reviewing the applications, CMS chose 15 highly qualified individuals to serve on the panel. The Panel was convened for the first time on February 27, February 28, and March 1, 2001. We published a notice in the **Federal Register** on February 12, 2001 (66 FR 9857) to announce the location and time of the Panel meeting, a list of agenda items, and that the meeting was open to the public. We also provided additional information through a press release and our website.

2. Specific Recommendations of the Advisory Panel and Our Responses

In this section of the proposed rule, we summarize the issues considered by the Panel, the Panel's APC recommendations, and our subsequent action with regard to the Panel's recommendations. The data used by the Panel in making its recommendation are the 1996 claims that were used to set the APC weights and payment rates for CY 2000 and 2001.

As discussed below, the Panel sometimes declined to recommend a change in an APC even though the APC violated the 2 times rule. In section II.C.3 of this preamble, we discuss our proposals regarding the 2 times rule based on the data we are using to recalibrate the 2002 APC relative weights (that is, claims for services furnished on or after July 1, 1999 and before July 1, 2000). That section also details the criteria we use in deciding to make an exception to the 2 times rule. We asked the Panel to review many of the exceptions we implemented in 2000 and 2001. The exceptions are referred to as ''violations of the 2 times'' rule in the following discussion.

APC 0016: Level V Debridement & Destruction

APC 0017: Level VI Debridement & Destruction

We asked the Panel to review the current placement of CPT code 56501, Destruction of lesion(s), vulva; simple, any method, in APC 0016 because the APC violates the 2 times rule. Because the procedure is a simple destruction of skin and superficial subcutaneous tissues, we would not expect it to have a median cost of $500. Thus, we believe that the higher costs associated with this code were the result of incorrect coding. To ensure that procedures in APC 0016 comply with the 2 times rule, we asked the Panel to consider one of the following clinical options:

- Move CPT code 56501 to APC 0017.
- Retain CPT code 56501 in APC 0016 but split APC 0016 into three APCs to distinguish simple destruction lesions from extensive destruction lesions.

The Panel rejected the option to split APC 0016 into three different APCs. The members stated that there was no validity in taking that approach because simple versus extensive destruction of lesions had greater significance in relation to physician work than in measuring facility resource use. They believed that many of the procedures assigned to APC 0016 are performed in a procedure room rather than in the operating room. The Panel considered factors such as the use of anesthesia and the method used to destroy the lesions as indicators of differences in facility resource consumption between simple and extensive destruction of lesions. The Panel agreed that the simple destruction of lesions should be assigned to the same APC as the extensive destruction of lesions if a laser is used to remove simple lesions. In this case, the Panel stated that the similarity in resource use is based on the method or technique used to perform the procedure.

The Panel also noted that CPT code 11042, Debridement; skin, subcutaneous tissue, and muscle, is the most frequently performed procedure in APC 0016, accounting for approximately 85 percent of this APC's total volume. The Panel noted that this code had probably been billed incorrectly because of widespread misunderstanding about its definition.

The Panel also reviewed procedures assigned to APCs 0014 (Level III Debridement & Destruction) and 0015 (Level IV Debridement & Destruction) and compared similarities and differences among those procedures and the ones assigned to APCs 0016 and 0017. During this comparative review, the Panel compared CPT code 56501 to the following two CPT codes: 46917, Destruction of lesion(s), anus, simple; laser surgery, which is assigned to APC 0014, and 54055, Destruction of lesion(s), penis, simple; electrodesiccation, which is assigned to APC 0016. In reviewing these three procedures, the Panel questioned whether the resources involved supported their current APC assignments. After considerable discussion, the Panel recommended the following:

- Move CPT code 56501 from APC 0016 to APC 0017.
- Move CPT code 46917 from APC 0014 to APC 0017.

The Panel recommended these changes to achieve clinical coherence and resource similarity among the procedures assigned to these APCs. Because CPT code 46917 is performed using laser equipment and requires anesthesia, the Panel believed it appropriate to move this procedure to APC 0017. Although the Panel considered the reassignment of CPT code 54055 to APC 0017, it did not recommend this change. The Panel's recommended changes would group in APC 0017 simple destruction of lesion procedures that use laser or surgical techniques with extensive destruction of lesion procedures.

We propose to accept the Panel's recommendation regarding CPT code 56501 and to revise the APC accordingly. However, as shown below in Table 3, we are proposing to make

additional changes to these APCs because of the 2 times rule.

APC 0024: Level I Skin Repair

APC 0025: Level II Skin Repair

APC 0026: Level III Skin Repair

APC 0027: Level IV Skin Repair

The composition of procedures in APCs 0025 and 0027 results in these APCs violating the 2 times rule. Therefore, we requested the Panel's advice in exploring other clinical options for reconfiguring the four skin repair APCs to achieve clinical and resource homogeneity among the procedures assigned to APCs 0025 and 0027 while retaining clinical and resource homogeneity for APCs 0024 and 0026. We asked the Panel to consider the following clinical options to achieve this result:

- Rearrange the procedures assigned to APCs 0024 through 0027 based on the size or the length of the skin incision.
- Rearrange the procedures assigned to APCs 0024 through 0027 based on the complexity of the repair, such as distinguishing repairs that involve layers of skin, flaps, or grafts from those that do not.

The Panel reviewed the various options presented, which were modeled based on the 1996 claims data used in constructing the current APC groups and payment rates. Using these data, the Panel discussed size and complexity of the various repairs, considered the clinical differences in performing the repairs on different anatomical sites, and the clinical differences involved in making skin repairs using flaps and grafts versus layers of skin. As a result of its review, the Panel stated that they found no compelling clinical advantages in the options presented. The Panel also agreed that more current data would be needed to make appropriate recommendations about the actual merits and benefits of the various options. For these reasons, the Panel recommended the following:

- Make no changes to APCs 0024 and 0027.
- Reevaluate these APCs with new data when the Panel meets in 2002.
- The Panel, in preparation for the 2002 meeting, will discuss with and gather clinical and utilization information from their respective hospitals regarding these procedures.

We propose to accept the Panel's recommendations. However, as shown in Table 3, we are proposing to make changes to these APCs based on the use of new data and application of the 2 times rule.

APC 0058: Level I Strapping and Casting Application

APC 0059: Level II Strapping and Casting Application

APC 0058 (which consists of the simpler casting, splinting, and strapping procedures) violates the 2 times rule. The median costs for high volume procedures in APC 0058 vary widely, ranging from $27 to $83. The median costs associated with presumably more resource-intensive procedures in APC 0059 are fairly uniform, ranging from $69 to $119. To limit the cost variation in APC 0058, we asked the Panel to consider the following options:

- Move the following four codes from APC 0058 to APC 0059: CPT code 29515, Application of short splint (calf to foot); CPT code 29520, Strapping; hip; CPT code 29530, Strapping; knee; and CPT code 29590, Denis-Brown splint strapping.
- Create a new APC to include a third level of strapping and casting application procedures by regrouping all procedures assigned to both APCs 0058 and 0059 based on the following clinical distinctions: Removal/revision, strapping/splinting, and casting.
- Package certain CPT codes assigned to APC 0058 with relevant procedures.

The Panel discussion revealed that codes grouped in APC 0058 are not always appropriately billed by hospitals. The Panel pointed out that code descriptors such as ''strapping of the hip'' are not commonly understood by hospital staff. The Panel noted that before implementation of OPPS, hospitals billed the items described by these codes as supplies (without a CPT code) when they were billed as anything other than an emergency room visit. They also stated that the use of these codes has been confused with the use of some codes associated with durable medical equipment. For these reasons, the Panel believed that the procedure costs reflected in our data are skewed. As a result, the Panel recommended that we do the following:

- Make no changes to APC 0058.
- Provide appropriate education and guidance to hospitals regarding appropriate use and billing of codes in APC 0058.
- Resubmit APC 0058 to the Panel for reevaluation when later data are available.

We propose to accept the Panel's recommendations except that we propose to move CPT code 29515 to APC 0059 due to the 2 times rule and the newer data we are using for this proposed rule.

APC 0079: Ventilation Initiation and Management

The codes in APC 0079 represent respiratory treatment and support provided in the outpatient setting. The cost variation among the assigned procedures in this APC raises concern about hospital coding practices. The median costs for these procedures range from $40 to $315. We asked the Panel to clarify whether these procedures are performed on outpatients or if they are performed on patients who come to the emergency room and are later admitted to the hospital as inpatients.

The Panel acknowledged that there are major problems associated with appropriately assigning codes to these procedures which results in incorrect billing. The Panel concluded that additional information is necessary to better understand the issues raised. The Panel also advised that CPT code 94660, Continuous positive airway pressure ventilation (CPAP), initiation and management, is a sleep apnea procedure used in the treatment of obesity and is clinically different from all other procedures in APC 0079. For these reasons, the Panel recommended the following:

- Remove CPT code 94660 from APC 0079 and create a new APC for this one procedure.

We propose to accept the Panel's recommendation by creating a new APC 0065, CPAP Initiation.

APC 0094: Resuscitation and Cardioversion

We requested the Panel's assistance in determining whether it is clinically appropriate to remove the cardioversion procedures from APC 0094 because the rest of the procedures assigned to APC 0094 are emergency procedures rather than elective. We proposed that the Panel consider the creation of a new APC for the cardioversion procedures or reassignment of the procedures to another APC that would be more appropriate in terms of clinical coherence and resource similarity. Splitting APC 0094 into two distinct groups, one for resuscitation procedures and the other for internal and external electrical cardioversion procedures, would not result in a significant difference in the APC payment rate for either of the new APCs.

The Panel considered whether it was clinically appropriate to combine internal and external cardioversion procedures (CPT codes 92960 and 92961, respectively) in the same APC. The Panel also questioned the conditions under which internal cardioversion procedures would be performed on an outpatient basis.

The Panel recommended that the only action we should take is to move CPT code 92961, Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure), from APC 0094 to APC 0087, Cardiac Electrophysiology Recording/Mapping.

We propose to accept the APC Panel recommendation.

APC 0102: Electronic Analysis of Pacemakers/Other Devices

The neurologic procedures included in APC 0102 (CPT codes 95970 through 95975), are significantly more complex than the routine cardiac pacemaker programming codes also assigned to this APC. Because we believe these codes are clinically different, we asked the Panel to consider the following:

- Create a new APC for the neurologic codes.
- Move the neurologic codes to APC 0215, Level I Nerve and Muscle Tests.

One presenter appearing before the Panel stated that APC 0102 involves clinical functions related to four different categories of devices; that is, pacemakers, defibrillators, infusion pumps, and neurostimulators. The presenter, who represented a device manufacturers' association, contended that these four categories of devices differ clinically. The presenter also stated that patients receiving these devices are clinically different and are even treated by different hospital departments. The presenter recommended the following:

- Split APC 0102 into two APCs: One APC for electronic analysis of pacemakers and other cardiac devices and a separate APC for electronic analysis of infusion pumps and neurostimulators.
- The APC created for electronic analysis of infusion pumps and neurostimulators would include the following CPT codes:

Code	Descriptor
62367 ..	Analyze spine infusion pump.
62368 ..	Analyze spine infusion pump.
95970 ..	Analyze neurostim, no prog.
95971 ..	Analyze neurostim, simple.
95972 ..	Analyze neurostim, complex.
95973 ..	Analyze neurostim, complex.
95974 ..	Cranial neurostim, complex.
95975 ..	Cranial neurostim, complex.

- The APC created for electronic analysis of pacemakers and other cardiac devices would include the following CPT codes:

Code	Descriptor
93727 ..	Analyze ilr system.
93731 ..	Analyze pacemaker system.
93732 ..	Analyze pacemaker system.
93733 ..	Telephone analy, pacemaker.
93734 ..	Analyze pacemaker system.
93735 ..	Analyze pacemaker system.
93736 ..	Telephone analy, pacemaker.
93737 ..	Analyze cardio/defibrillator.
93738 ..	Analyze cardio/defibrillator.
93741 ..	Analyze ht pace device sngl.
93742 ..	Analyze ht pace device single.
93743 ..	Analyze ht pace device dual.
93744 ..	Analyze ht pace device dual.

The presenter stated that reorganizing APC 0102 as recommended would establish groups that are more clinically and resource similar than the current grouping. The presenter believes that APC 0102 as currently configured violates the 2 times rule. The median costs for the 21 procedures currently included in APC 0102 vary from $19 to $145. Other presenters clarified clinical aspects of the procedures, identified which practitioners perform them, the time it takes to perform them, and how they are to be billed. Yet another presenter speaking on behalf of a specialty society noted that the society had previously commented on this APC and requested that we remove CPT codes 93737 and 93738 from APC 0102.

The Panel noted that because most of the codes are new, having been established since 1996 (the base year of data available to the Panel), these newer procedures could not have been included in the data file used to create the current APC payment rates. In the absence of frequency and median cost data for many of these procedures, the Panel was concerned about reorganizing the codes in this APC. Nonetheless, the Panel recommended the following reorganization of APC 0102 to better reflect clinical coherence:

- APC 0102 be split into four new APCs: One APC for analysis and programming of infusion pumps and CSF shunts; a second for analysis and programming of neurostimulators; a third for analysis and programming of pacemakers and internal loop recorders; and a fourth for analysis and programming of cardioverter-defibrillators.

We propose to accept the Panel's recommendations and propose to create four new APCs as follows:

APC 0689: Electronic Analysis of Cardioverter-Defibrillator

APC 0690: Electronic Analysis of Pacemakers and Other Cardiac Devices

APC 0691: Electronic Analysis of Programmable Shunts/Pumps

APC 0692: Electronic Analysis of Neurostimulator Pulse Generators.

APC 0110: Transfusion

APC 0111: Blood Product Exchange

APC 0112: Extracorporeal Photopheresis

The procedures included in APC 0110 are those related only to the services associated with performing the blood transfusion and monitoring the patient during the transfusion; the costs associated with the blood products themselves are not included in APC 0110. We advised the Panel that we were not certain that cost data for blood transfusions excluded the costs of the blood products because the APC 0110 median cost of $289 seemed excessive. We expressed concern about hospital coding and billing practices for blood products, blood processing, storage, and transportation charges as represented in the 1996 data. We asked the Panel to advise us on how to clarify hospital billing and coding practices for blood transfusions; we also asked if the Panel members believe that the median costs for transfusion procedures include the costs for blood products and, if so, how the procedures should be adjusted to eliminate these costs.

A presenter representing a device manufacturers' association noted that these issues were examined extensively by several specialty societies that sent considerable data to us on the actual cost of the transfusion procedures before publication of the April 7, 2000 final rule (65 FR 18434). The presenter stated that the median costs for transfusion procedures that we used in calculating the final payment rate for APC 0110 was somewhat lower than the costs submitted by the specialty societies. The presenter believes that our experience under the APC system is too limited for us to make a judgment concerning the validity of the median costs. The presenter also believes that the payment rate for APC 0110 should have been adjusted to include costs for blood safety tests, such as the hepatitis and HIV look-back tests mandated by the FDA over the past several years, because these costs were not included in the 1996 data used to construct the APC rates. The presenter stated that these tests are expensive and that they increase the hospitals' costs to provide the blood. However, it was unclear whether these tests are separately billable under the lab fee schedule.

In addition, the presenter explained that blood centers do not charge hospitals for blood because it is voluntarily donated, not manufactured. The presenter stated that blood centers charge hospitals what it costs them to provide the blood and that hospitals bill

acquisition and processing charges rather than charges for the blood itself. Based on the information provided, the presenter urged the Panel not to revise APC 0110 until more data become available.

For APC 0111, another representative of a specialty society recommended that CPT code 36521, Therapeutic apheresis; with extracorporeal affinity column absorption and plasma reinfusion, be moved from APC 0111 to APC 0112. The presenter stated that CPT code 36521 is more similar clinically and in resource use to 36522, Photopheresis, extracorporeal which is in APC 0112. The presenter stated that a major difference between the procedure represented by CPT codes 36521 and 36520, Therapeutic Apheresis; plasma and/or cell exchange, which is also assigned to APC 0111, and the other procedures codes assigned to APC 0111, is that hospitals can bill separately for blood products such as the plasma or albumin used in performing plasma exchange procedures. The presenter described CPT code 36521 as a ''self-contained'' procedure not requiring the use of albumin or plasma, because the patient's own blood is processed through a machine and returned to the patient. The presenter stated that the materials and equipment used to perform this procedure make it much more costly than the other procedures assigned to APC 0111. The presenter, citing cost data from two medical centers where CPT code 36521 is frequently performed, stated that the total cost of the procedure, including the cost of the adsorption column, is approximately $2000. At this time, the commenter noted, only one of the adsorption columns (Prosorba) used for this procedure is eligible for transitional pass-through payments, which means that payments for this procedure, which are based upon the APC payment alone, are too low when one of the other columns is used and no additional pass-through payment is made. It was stated that the cost of many of the adsorption columns is over $1000 per column. The presenter concluded that moving CPT code 36521 from APC 0111 to APC 0112 would comply with the statutory requirements for clinical coherence and resource similarity among procedures in the same APC.

The Panel discussed various adsorption devices used in performing CPT code 36521, their eligibility for transitional pass-through payments, as well as the clinical and resource use difference between CPT codes 36520 and 36551. After considerable discussion, the Panel recommended the following:

- Take no action on APC 0110.
- Move CPT code 36521 from APC 0111 to APC 0112 to achieve clinical coherence and resource similarity with photopheresis procedures included in APC 0112. However, the Panel cautioned that the payment for APC 0112 captured the cost of the entire procedure including the cost of the adsorption column. For this reason, any additional payment for the adsorption column through the transitional pass-through payment mechanism would be a duplicate payment. Therefore, the panel asked that CMS address this problem when considering their recommendation.

We propose to accept the Panel's recommendations. We note that effective April 1, 2001, the Prosorba column is no longer eligible for a transitional pass-through payment (see PMA–01–40 issued on March 27, 2001).

APC 0116: Chemotherapy Administration by Other Technique Except Infusion

APC 0117: Chemotherapy Administration by Infusion Only

APC 0118: Chemotherapy Administration by Both Infusion and Other Technique

We had received several comments requesting that oral delivery of chemotherapy and delivery of chemotherapy by infusion pumps and reservoirs be recognized for payment under the OPPS. We asked the Panel to examine this issue.

With regard to oral administration of chemotherapy, the Panel heard several presenters discuss the need for extensive beneficiary education prior to administration of oral anticancer agents. The Panel agreed that the beneficiaries actually self-administer the drug and that beneficiary education was appropriately billed as a clinic visit. The Panel stated that this would be true whether the education involved cancer chemotherapy, diabetes management, or congestive heart failure management. Therefore, the Panel recommended that no new codes be created to specifically recognize oral administration of chemotherapy.

With regard to recognizing chemotherapy administration through infusion pumps and ports, the Panel heard several presentations that this is becoming a common method of administering not only cancer chemotherapy but also for administering other types of pharmaceuticals. It was pointed out that because CPT codes 96520, Refilling and maintenance of portable pump, and 96530, Refilling and maintenance of implantable pump or reservoir, were excluded from the OPPS it was impossible for hospitals to be paid when performing these services. After lengthy discussion, the Panel recommended that refilling and maintenance of pumps and reservoirs be assigned to an APC.

The Panel also discussed the current HCPCS Q codes for chemotherapy administration and concluded that these codes should continue to be recognized in the OPPS. In addition, the Panel discussed whether a new Q code should be developed for extended chemotherapy infusions.

In summary, the Panel recommended the following:

- Hospitals be allowed to bill for patient education under the appropriate clinic codes.
- CPT codes 96520 and 96530 be assigned to a new APC.
- The current HCPCS Level II Q codes for chemotherapy administration should continue to be used.
- There is no need to develop a new HCPCS code for ''extended chemotherapy infusions.''
- CMS should consider developing a new HCPCS code for flushing of ports and reservoirs.

We propose to accept all the Panel recommendations except for the recommendation regarding flushing of ports and reservoirs. Flushing is performed in conjunction with either a chemotherapy administration service or an outpatient clinic visit. In the first case, flushing is part of the chemotherapy administration and its costs are adequately captured in the costs of the chemotherapy administration code. In the second case, we believe that the costs of flushing are adequately captured in the costs of the clinic visit and need not be paid separately. We are proposing to create a new APC 0125, Refilling of Infusion Pump.

APC 0123: Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant

In APC 0123, the 1996 median cost for CPT code 38230, Bone marrow harvesting for transplantation, was only $15. We believe that this cost is lower than the actual cost of the procedure. Further, we do not have sufficient data to determine how often bone marrow and stem cell transplant procedures are performed on an outpatient basis. For these reasons, we requested the Panel's advice in clarifying the resources used in performing the procedures assigned to APC 0123, and the extent to which these procedures are performed on an outpatient basis.

The Panel noted that these transplant and stem cell harvesting procedures are

being increasingly performed on an outpatient basis. One presenter representing a specialty society stated that 95 percent of these procedures are performed in the hospital outpatient setting. The presenter shared cost data from the bone marrow transplant unit of an academic medical center that showed the cost to harvest bone marrow to be about $1,800. The presenter observed that this cost is significantly higher than the APC payment rate of about $205 for APC 0123. Another presenter representing a group of hospitals stated that the supply costs alone for bone marrow harvesting are more than the current APC payment for the procedure. The presenter suggested that miscoding may have contributed to the low $15 median cost reflected in our database. After discussion, the Panel recommended the following:

- Make no changes in the procedures assigned to APC 0123 in the absence of sufficient data to support such modifications.
- The two presenters on this APC issue submit cost data for the Panel to use in reevaluating this issue at its 2002 meeting.

We note that our analysis of the more recent claims data we are using to reclassify and recalibrate the APCs in this proposed rule reveals a significant increase in costs for this APC resulting in a proposed payment rate that is double the current rate. However, very few procedures (fewer than 20) were billed on an outpatient basis. We will have the Panel review this APC again at their next meeting.

APC 0142: Small Intestine Endoscopy

APC 0143: Lower GI Endoscopy

APC 0145: Therapeutic Anoscopy

APC 0147: Level II Sigmoidoscopy

APC 0148: Level I Anal/Rectal Procedures

APC 0149: Level II Anal/Rectal Procedures

APC 0150: Level III Anal/Rectal Procedures

We presented these seven APCs to the Panel because of the inconsistencies in the median costs for some procedures included in APCs 0142, 0143, 0145, and 0147. We advised the Panel that our cost data do not show a progression of median costs proportional to increases in clinical complexity as we would expect. For example, the data indicate that a therapeutic anoscopy assigned to APC 0145 costs more than twice as much as a flexible or rigid sigmoidoscopy assigned to APC 0147. We stated our concern that cost disparity could provide incentives to use inappropriate procedures. Because of these concerns, we asked the Panel's advice in determining whether one of the following actions should be taken:

- Divide the codes in APC 0142 into separate APCs representing ileoscopy and small intestine procedures.
- Combine diagnostic anoscopy and Level I sigmoidoscopy.
- Merge APCs 0143, 0145, and 0147 into one APC.

We also asked the Panel whether the costs associated with codes in APC 0145 appeared to be valid.

During the Panel discussion, it was noted that the data distributed to the Panel for these APCs indicated that most of the procedures are billed as single procedures only 50 percent of the time. This raised questions as to whether the data include procedures such as flexible sigmoidoscopies that were miscoded as rigid sigmoidoscopies, colonoscopies, and anoscopies. In examining the data, the Panel considered what impact this miscoding would have on the cost data, and discussed the clinical approaches used to perform some of the procedures, what type of practitioners perform them, and other procedures and supplies that would be billed with them. As a result of this discussion, the Panel concluded that the data anomalies were probably attributable to miscoding because hospitals have not received sufficient guidance and information on appropriately coding procedures included in these APCs. The Panel also agreed that it would need more current data before it could consider reconfiguring these APCs. Therefore, the Panel recommended that we do the following:

- Make no changes to APCs 0142, 0143, 0145, and 0147.
- Provide information and guidance to better assist hospitals in understanding how to bill appropriately for services included in APCs 0142, 0143, 0145, and 0147.
- Resubmit these APCs to the Panel for review when newer data are available.

We propose to accept the Panel's recommendations.

APC 0151: Endoscopic Retrograde Cholangio-Pancreatography (ERCP)

We advised the Panel that we have received comments that indicate that it is inappropriate to assign both diagnostic and therapeutic ERCP procedures to the same APC. The commenters allege that virtually every hospital performs diagnostic ERCPs but only teaching hospitals perform therapeutic ERCPs. Based on our current data, if we created two APCs for ERCP procedures, the APC payment rate for therapeutic ERCPs would be lower than that for diagnostic ERCPs (approximately $526 and $535, respectively). Therefore, we requested the Panel's advice to help us determine whether to create separate APCs for diagnostic and therapeutic ERCP procedures.

A presenter speaking on behalf of a specialty society made the following points:

- ERCP is the most complex endoscopy procedure to perform and is usually performed by gastroenterologists.
- ERCP is usually performed at large hospitals.
- The most complex ERCP procedures are usually performed in teaching hospitals.
- Current payments for ERCP are lower than the costs to perform the procedure (based on cost and frequency data gathered from several teaching hospitals).
- Single claims should not be used to calculate an APC payment rate for ERCP services because a single ERCP procedure usually consists of several components, each with its own CPT code (e.g., sphincterotomy and stent placement). Therefore, an ERCP billed as a single CPT code would represent aberrant billing and would not accurately reflect the costs of an ERCP.

The OPPS data distributed to the Panel verified that the vast majority of the ERCP procedures are performed as multiple procedures. The Panel agreed that the use of single claims data could possibly skew the APC payment rate for ERCP services.

The Panel recommended that we do the following:

- Do not reconfigure the ERCP procedures in APC 0151.
- Resubmit this issue to the Panel for review when more recent data are available.
- Explore the feasibility of using multiple claims rather than single claims to calculate appropriate APC payment rates for ERCP procedures.

We propose to accept the Panel's recommendations. We are currently reviewing the potential for using multiple claims data for determining payment rates for ERCP procedures. As a first step in the process, in this proposed rule, we have determined a payment rate for ERCP procedures based on both single claims for ERCP procedures and, because ERCP procedures are typically done under radiologic guidance, on claims that included both an ERCP procedure and a radiologic supervision or guidance

procedure in this APC. Using these additional claims has resulted in significantly increasing the number of claims used to determine the payment rate for this APC and in a much higher proposed payment rate (about $825).

APC 0160: Level I Cystourethroscopy and other Genitourinary Procedures

APC 0161: Level II Cystourethroscopy and other Genitourinary Procedures

APC 0162: Level III Cystourethroscopy and other Genitourinary Procedures

APC 0163: Level IV Cystourethroscopy and other Genitourinary Procedures

APC 0169: Lithotripsy

We advised the Panel that we had received a number of comments that advocated moving CPT code 52337, Cystoscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included), from APC 0162 to APC 0163. (We note that CPT code 52337 was deleted for 2001 and replaced with an identical CPT code, 52353. We will use the new code in the following discussion.) Because of these comments, we sought the Panel's advice in examining the clinical and resource distinctions between CPT code 52353 and other procedures assigned to APC 0162. Other information shared with the Panel noted that most of the procedures included in APC 0162 are complicated cystourethroscopies while those assigned to APC 0163 are largely prostate procedures.

One presenter representing a device manufacturer discussed the merits of reassigning CPT code 52353 to either APC 0163 or 0169 (APC 0169 contains a single CPT code, 50590, Lithotripsy, extracorporeal shock wave (ESWL)). The presenter was concerned that our decision to assign the cystourethroscopic procedure to APC 0162 rather to APC 0163 was not explained in our April 7, 2000 final rule.

Furthermore, the presenter noted that this decision resulted in a 40 percent decline in payment for the procedure which will make it difficult for hospitals to provide this service because the capital equipment, probes, and fibers required to perform the procedure are expensive. Moreover, the probes and fibers are ineligible for transitional pass-through payments because they are not single-use items. At the Panel's request, the presenter discussed the clinical differences between CPT codes 52353 and 50590. The presenter stated that code 50590 is a noninvasive procedure that involves breaking up kidney stones using shock waves produced outside the patient while code 52353 is an invasive procedure that requires the urologist to insert different instruments through a cystoscope and a uretheroscope to access stones in the upper urinary tract (the ureter and kidney).

The presenter also compared the cost of performing CPT code 52353 with that for CPT code 52352, which involves the mechanical removal of stones. The presenter asked the Panel to consider the following two options to resolve this issue:

- Reassign CPT code 52353 to APC 0169, Lithotripsy. The presenter believes that this would be the most appropriate assignment clinically and from a cost perspective because both involve lithotripsy and require expensive capital equipment, fibers, and probes. Also, other payers using a similar procedure grouping system, ambulatory procedure groups (APGs), have grouped these procedures together.
- Restore CPT code 52353 to its original APC assignment, APC 0163.

In addition, the presenter expressed concern that the large number of procedures assigned to APC 0162 makes it difficult to achieve clinical homogeneity within the APC. The presenter asked that we work with appropriate groups to reconfigure APC 0162 because, as constituted, it appears to violate the 2 times rule.

The Panel had a lengthy discussion regarding whether to move CPT code 52353 to APC 0163 or to APC 0169. The Panel considered the resources used for procedures in APCs 0163 and 0169 and noted that the lithotriptor used for code 50590 may be purchased or leased and that lease rates for lithotriptors have frequently been inflated. Furthermore, it noted that much of the equipment and resource use required for code 52353 is similar to the resource use of other procedures in APC 0163. In spite of these considerations, the Panel voted eight to seven to recommend moving CPT code 52353 from APC 0162 to APC 0169 because both codes 52353 and 50590 are lithotripsy procedures.

We reviewed the panel discussion very carefully and noted the close vote. After careful consideration, we propose to disagree with the Panel's recommendation and move code 52353 to APC 0163. The 1999–2000 cost data, which contains over 400 single claims for code 52353 and over 6,000 single claims for code 50590, show that the median cost for code 52353 is much more similar to the median cost of other procedures in APC 0163 than it is to the median cost of APC 0169. Although both codes involve lithotripsy, the type of equipment used in the two procedures is very different. Clinically, the surgical approach used for code 52353 and the resources used (e.g., anesthesia and operating room costs) are much more similar to other procedures in APC 0163 than to those for code 50590. Additionally, the median cost for code 50590, which is $700 higher than that of code 52353, is dependent on the widely variable arrangements hospitals make for use of the extracorporeal lithotriptor. Therefore, we believe that placing code 52353 in APC 0163 maintains its clinical coherence and similar use of resources.

APC 0191: Level I Female Reproductive Procedures

APC 0192: Level II Female Reproductive Procedures

APC 0193: Level III Female Reproductive Procedures

APC 0194: Level IV Female Reproductive Procedures

APC 0195: Level V Female Reproductive Procedures

This group of APCs was presented to the Panel because APC 0195 violates the 2 times rule. To facilitate the Panel's review of this issue, we distributed cost data on all the female reproductive procedures assigned to these five APCs. These data showed that the median costs for procedures assigned to APC 0195 ranged from a low of $365 to a high of $1,817. The CPT code 57288, Sling operation for stress incontinence (e.g., fascia or synthetic), which is assigned to APC 0195, has the highest median cost of the procedures in this group. We discussed with the Panel two clinical options for rearranging the procedures assigned to APC 0195 to comply with the 2 times rule. The first option would split APC 0195 into two separate APCs by separating vaginal procedures from abdominal procedures. The second option would split APC 0195 into three distinct APCs by retaining the separate APCs for abdominal and vaginal procedures and further distinguishing vaginal procedures based on whether they are simple or complex.

The Panel discussed the rapid increase in the rate at which CPT code 57288 is performed on an outpatient basis. The Panel stated that this procedure is becoming more routine and replacing many of the older, more complex urinary dysfunctional procedures. Questions were raised about the frequency with which this procedure is performed alone as opposed to being performed as one of several procedures. The Panel was advised that the sling material and the relevant anchors used in performing

CPT code 57288 are eligible for transitional pass-through payments.

One presenter, speaking on behalf of a device manufacturer, supported our proposal to divide APC 0195 into different clinical groupings. The presenter's testimony was limited to a discussion of CPT code 57288. The presenter concurred with the Panel's assessment of the current utilization trends for CPT code 57288, emphasized the high costs associated with performing this procedure, and highlighted the wide variation in techniques and devices used to perform it. Because of these factors, the presenter believes that the procedure is underpaid and that the 1996 cost data may not fully reflect the actual costs associated with performing CPT code 57288.

The Panel also closely reviewed the other four APCs for female reproductive procedures to ensure each was clinically homogeneous. As a result of this review, the Panel recommended a number of changes for these APCs. These recommendations and those for APC 0195 are as follows:

- Move CPT codes 56350, Hysteroscopy, diagnostic, and 58555, Hysteroscopy, diagnostic/separate procedure, from APC 0191 to APC 0194 (In 2001, CPT code 56350 was replaced with CPT code 58555.)
- Divide APC 0195 into two APCs to distinguish vaginal procedures from abdominal procedures.
- Retain the following vaginal procedures in APC 0195:

CPT code	Descriptor
57555	Excision of cervical stump, vaginal approach: with anterior and/or posterior repair.
58800	Drainage of ovarian cyst(s), unilateral or bilateral, (separate procedure); vaginal approach.
58820	Drainage of ovarian abscess; vaginal approach, open.
57310	Closure of urethrovaginal fistula.
57320	Closure of vesicovaginal fistula; vaginal approach.
57530	Trachelectomy (cervicectomy), amputation of cervix (separate procedure).
57291	Construction of artificial vagina; without graft.
57220	Plastic operation on urethral sphincter, vaginal approach (e.g., Kelly urethral plication).
57550	Excision of cervical stump, vaginal approach.
57556	Excision of cervical stump, vaginal approach; with repair of enterocele.
57289	Pereyra procedure, including anterior colporrhaphy.
57300	Closure of rectovaginal fistula; vaginal or transanal approach.
57284	Paravaginal defect repair (including repair of cystocele, stress urinary incontinence, and/or incomplete vaginal prolapse).
57265	Combined anteroposterior colporrhaphy; with enterocele repair.
57268	Repair of enterocele vaginal approach (separate procedure).
56625	Vulvectomy simple; complete.
58145	Myomectomy excision of fibroid tumor of uterus, single or multiple (separate procedure); vaginal approach.
57260	Combined anteroposterior colporrhaphy.
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele.
57250	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy.
56620	Vulvectomy simple; partial.
57522	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; loop electrode excision.

- Include the following abdominal procedures in a new APC titled ''Level VI Female Reproductive Procedures.''

CPT code	Descriptor
58920	Wedge resection or bisection of ovary, unilateral or bilateral.
58900	Biopsy of ovary, unilateral or bilateral (separate procedure).
58925	Ovarian cystectomy, unilateral or bilateral.
57288	Sling operation for stress incontinence (e.g., fascia or synthetic).
57287	Removal or revision of sling for stress incontinence (e.g., fascia or synthetic).

- Move CPT code 57107 from APC 0194 to APC 0195, Level V Female Reproductive Procedures.
- Move CPT code 57109, Vaginectomy with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lympadenectomy and para-oortic lymph node sampling (biopsy), from APC 0194 to the new APC, Level VI Female Reproductive Procedures.

We propose to accept all of these Panel recommendations. These APCs would be reconfigured and renumbered as APCs 0188 to 0194. We are also proposing to add new APCs for Level VII and Level VIII Female Reproductive Procedures (APCs 0195 and 0202, respectively) based on the 1999–2000 claims data and the 2 times rule.

APC 0210: Spinal Tap

APC 0211: Level I Nervous System Injections

APC 0212: Level II Nervous System Injections

The Panel heard testimony from two presenters regarding the merits of modifying these three APCs. The first presenter, speaking on behalf of a manufacturer, discussed CPT code 64614, Chemodenervation of muscles; extremities and/or trunk muscles (e.g., for dystonia, cerebral palsy, multiple sclerosis). The presenter advised the Panel that although this is a new code for 2001, the procedure is well established and formerly coded using CPT code 64640, Destruction by neurolytic agent; other peripheral nerve or branch. The new code was created to distinguish chemodenervation of limb and trunk muscles from other chemodenervation procedures. The presenter claimed that this code is similar both clinically and in terms of resource use to the other chemodenervation procedures assigned to APC 0211, so it should be assigned to that APC instead of APC 0971, New Technology—Level II, where it is currently assigned.

The second presenter, representing a specialty society, proposed regrouping the procedures assigned to APCs 0210, 0211, and 0212 based on similar levels of complexity and median costs. The presenter's proposal also included reassignment to these APCs of interventional pain procedures

currently assigned to APCs 040, Arthrocenteris and Ligament/Tendon Injection, 0105, Revision/Removal of Pacemakers, AICD, or Vascular Device, and 0971. The presenter contended that it was essential to reconfigure these APCs because of disparity in resource use among procedures currently assigned to the same APC. The presenter also claimed that many of these procedures are being underpaid in their current APC and, for that reason, a number of hospitals have chosen not to perform them in the outpatient setting. The presenter proposed establishing the following five levels of interventional pain procedures by regrouping the procedures into new APCs as stated below:

• Level I Nerve Injections (to include Trigger Point, Joint, Other Injections, and Lower Complexity Nerve Blocks):

CPT code	Reassigned from APC
20550	040
20600	040
20605	040
20610	040
64612	0211
64613	0211
64614	0971
64400–64418	0211
64425	0211
64430	0211
64435	0211
64445	0211
64450	0211
64505	0211
64508	0211

• Level II Nerve Injections (to include Moderate Complexity Nerve Blocks and Epidurals):

CPT code	Reassigned from APC
27096	0210
62270	0210
62272	0210
62273	0212
62310–62319	0212

Level III Nerve Injections (to include Moderately High Complexity Epidurals, Facet Blocks, and Disk Injections):

CPT code	Reassigned from APC
62280–62282	0212
62290	Currently Packaged.
62291	Currently Packaged.
64420–64421	0211
64470	0211
64472	0211
64475–64476	0211
64479	0211
64480	0211
64483–64484	0211
64510	0211
64520	0211
64530	0211
64630	0211
64640	0211

• Level IV Nerve Injections (to include High Complexity Lysis of Adhesions, Neurolytic Procedures, Removal of Implantable Pumps and Stimulators):

CPT code	Reassigned from APC
62263	0212
64600	0211
64605	0211
64610	0211
64620	0211
64622–64623	0211
64626–64627	0211
64680	0211
62355	0105
62365	0105

• Level V Nerve Injections (to include Highest Complexity Disk and Spinal Endoscopies): CPT code 62287, Aspiration or decompression procedure, percutaneous, of nucleus pulposus of invertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous diskectomy, percutaneous laser diskectomy), reassigned from APC 0220, Level I Nerve Procedures.

The Panel recommended reassignment of CPT code 64614 from APC 0971 to APC 0211.

Concerning the suggested regrouping of interventional pain procedures, the Panel agreed that the recommended division of these procedures by clinical complexity would reflect resource use and was a reasonable approach to take. It was pointed out to the Panel that the costs for CPT codes 62290, Injection procedure for diskography, each level; lumbar, and 62291, Injection procedure for diskography, each level; cervical or thoracic, were packaged into the procedures with which they were billed. Therefore, the Panel concurred with the regrouping of procedures to establish Levels I, II, III, and IV with the following exceptions:

• The Panel recommended that CPT codes 62290 and 62291 not be included in Level III because they are packaged injections and should not be unpackaged and paid separately.

• The Panel opposed moving CPT codes 62355, Removal of previously implanted intrathecal or epidural catheter, and 62365, Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion, from APC 0105 to Level IV Nerve Injections because they were neither clinically similar nor similar in resource use to the other codes assigned to this proposed APC.

• The Panel opposed the creation of Level V Nerve Tests as it included only one code and recommended that CPT code 62287 remain in APC 220.

We propose to accept the Panel's recommendations for these services. We propose to create new APCs 0203, 0204, 0206, and 0207 to accommodate these proposed changes.

APC 0215: Level I Nerve and Muscle Tests

APC 0216: Level II Nerve and Muscle Tests

APC 0217: Level III Nerve and Muscle Tests

We advised the Panel that we had received a comment contending that assignment of CPT code 95863, Needle electromyography, three extremities with or without related paraspinal areas, to APC 0216 created an inappropriate incentive to perform tests on three extremities rather than two or four extremities. The payment of about $144 for APC 0216 is greater than the payment of about $58 for the same tests when performed on one, two, or four extremities. This is due to the fact that CPT codes 95860, 95861, and 95864, Needle electromyography, one, two, and four extremities with or without related paraspinal areas, respectively, are assigned to APC 0215. We distributed data to the Panel that showed a median cost of about $141 for CPT code 95863, which is more than 3 times that of the median cost of $41 for CPT code 95864. We asked the Panel to consider the reassignment of CPT code 95863 from APC 0216 to APC 0215 and advised the Panel that, based on cost data available at the time of our meeting, this change could potentially reduce the payment for APC 0216. It was also noted that this change could result in a payment increase for APC 0215.

The Panel reviewed the cost data for APCs 0215 and 0216 and noted that the median costs for both CPT codes 95863 and 95864 appeared aberrant. Based on the information presented, the Panel recommended that we move CPT code 95863 from APC 0216 to APC 0215.

We propose to accept the Panel's recommendation with one exception. We are proposing to revise these APCs based on the 1999–2000 cost data and the 2 times rule, and CPT code 95863 would be assigned to a reconfigured APC for Level II Nerve and Muscle Tests (APC 0218).

APC 0237: Level III Posterior Segment Eye Procedures

We advised the Panel that procedures assigned to APC 0237 are high volume procedures and rank among the top outpatient procedures billed under Medicare. We have received a number of comments disagreeing with the assignment of CPT code 67027, Implantation of intravitreal drug delivery system (e.g., ganciclovoir implant), which includes concomitant removal of vitreous, to APC 0237. This procedure was added to the CPT coding system after 1996 and, therefore, was not included in the 1996 data. We advised the Panel that ganciclovoir, the drug implanted during this procedure, is paid separately as a transitional pass-through item. Because the drug is paid separately, it should not be included in determining whether the resources associated with the surgical procedure are similar to the resources required to perform the other procedures assigned to APC 0237. We advised the Panel that, of the procedures assigned to APC 0237, we believe that CPT code 67027 is related to codes 65260, 65265, and 67005, all of which involve removal of foreign bodies and vitreous from the eye. To ensure that CPT code 67027 is assigned to the appropriate APC, we asked the Panel to consider creation of a new APC, Level IV Posterior Segment Eye Procedures, for CPT codes 65260, 65265, 67005, and 67027. Based on the APC rates effective January 1, 2001, the suggested change could lower the APC rate for the four procedures by $400.

The Panel reviewed the data and did not believe it was sufficient to support the creation of a new APC for these four procedures. Therefore, the Panel recommended that APC 0237 remain intact and that more recent claims data be analyzed to determine whether CPT code 67027 is similar to the other procedures assigned to APC 0237.

Based on the 1999–2000 claims data, we have determined that the resources used for code 67027 are similar to other procedures in APC 0237. However, we will present APCs 0235, 0236, and 0237 to the Panel at their next meeting to determine whether any further changes should be made. We are proposing to make various other changes to these APCs based on the new data and the 2 times rule.

APC 0251: Level I ENT Procedures

This APC violates the 2 times rule because it consists of a wide variety of minor ENT procedures, many of which are low volume services or codes for nonspecific procedures. In order to correct this problem, we proposed to the Panel that this APC be split by surgical site (e.g., nasal and oral). After reviewing cost data, the Panel agreed that the APC should be split but that current data were insufficient to determine how that split should be made. Therefore, the Panel asked that this APC, along with more recent cost data, be placed on the agenda at the next meeting.

We agree that this APC should be reviewed by the Panel at its next meeting. However, our review of the more recent cost data indicates that significant violations of the 2 times rule still exist. In order to correct this problem, but keep the APC as intact as possible, we propose to move CPT codes 30300, Remove foreign body, intranasal; office type procedure, 40804, Removal of embedded foreign body, vestiblue of mouth; simple, and 42809, Removal of foreign body from pharynx, to APC 0340, Minor Ancillary Procedures. This APC consists of procedures such as removal of earwax that require similar resources.

APC 0264: Level II Miscellaneous Radiology Procedures

We asked the panel to review this APC because it violated the 2 times rule and consisted of a wide variety of unrelated procedures. Specifically, we believe that the costs associated with CPT codes 74740, Hysterosalpingography, radiological supervision and interpretation, and 76102, Radiologic examination, complex motion (e.g., hypercycloidal) body section (e.g., mastoid polytomography), other than with urography; bilateral, were aberrant and that we would significantly underpay these procedures if we moved them into a lower paying APC. We also asked the Panel to determine whether this APC and APC 0263, Level I Miscellaneous Radiology Procedures, should be reconfigured by body system. After considerable discussion, the Panel agreed that the procedures in these APCs were not clinically homogeneous; however, it recommended that we leave these APCs intact because the data do not support any more coherent reorganization. The Panel requested that this APC be placed on the agenda for the 2002 meeting.

We agree with the Panel with the following revisions. First, BIPA requires us to assign procedures requiring contrast into different APCs from procedures not requiring contrast. This required changes to a number of radiologic APCs including APCs 0263 and 0264. In addition, in this proposed rule, we would move CPT code 75940, Percutaneous Placement of IVC filter, radiologic supervision and interpretation, to a new APC 0187, Placement/Reposition Miscellaneous Catheters, because its costs were significantly higher than the costs of the procedures remaining in APC 0264.

APC 0269: Echocardiogram except Transesophageal

APC 0270: Transesophageal Echocardiogram

We asked the Panel to consider splitting these APCs based on whether or not 2D imaging is employed. After review of the data, the Panel recommended that we leave these APCs intact.

We propose to leave APC 0270 intact except for the addition of two new codes for transesophageal echocardiography. We also propose to split APC 0269 into two APCs, APC 0269, Level I Echocardiogram Except Transesophageal and APC 0697, Level II Echocardiogram Except Transesophageal. One APC (0697) would include comprehensive echocardiograms and the other APC (0269) would include limited/follow-up echocardiograms and doppler add-on procedures.

APC 0274: Myelography

We advised the Panel that APC 0274 is clinically homogeneous but that it violates the 2 times rule. Procedures assigned to this APC include radiological supervision and interpretation of diagnostic studies of central nervous system structures (e.g., spinal cord and spinal nerves) performed after injection of contrast material. We shared data with the Panel that showed the median costs for the procedures assigned to this APC ranged from a low of about $109 to a high of about $295. We asked the Panel's recommendation for reconfiguring APC 0274 to comply with the 2 times rule.

We informed the Panel members that we packaged the costs associated with radiologic injection codes into the radiological supervision and interpretation codes with which they were reported. The reason for doing this is that hospitals incur expenses for providing both services and they typically perform both an injection and a supervision and interpretation procedure on the same patient. Therefore, since neither an injection code nor a supervision and interpretation code should be billed alone, it would not be appropriate for us to use single claims data to determine the costs of performing these procedures. However, we are using single claims data in order to accurately

determine the costs of performing procedures. Therefore, in order to accurately determine the costs of a complete radiologic procedure, we had to package the costs of the injection component into the cost of the supervision and interpretation component with which it was billed. The Panel believed that, in 1996, hospitals generally did not bill the injection code when performing myelography. Furthermore, in 1996, some hospitals kept patients overnight after a myelogram. More recently, postmyelogram recovery time has decreased to about 6 hours. For these reasons, the Panel believed that the median costs of $109 and $174 probably do not represent the actual resources used for CPT codes 70010, Myelography, posterior fossa, radiological supervision and interpretation, and 70015, Cisternography, positive contrast, radiological supervision and interpretation. Therefore, the Panel recommended the following:

- Make no changes to APC 0274.
- Review new cost data to determine whether payment would increase for APC 0274.

We propose to accept the Panel's recommendations.

APC 0279: Level I Diagnostic Angiography and Venography

APC 0280: Level II Diagnostic Angiography and Venography

We presented these codes to the Panel for several reasons. APC 0279 fails the 2 times rule, there are numerous codes in these APCs with no cost data, there are numerous ''add on'' codes in these APCs, and many of these procedures were performed infrequently in the outpatient setting in 1996.

The Panel reviewed the clinical coherence of both APCs as well as the resources required to perform all these procedures. The Panel believed that it would be unusual for many of these procedures to be performed separately and that we would need to look at multiple claims to get accurate data. The Panel recommended the following:

- Create a new APC (APC 0287, Complex Venography) with the following CPT codes: 75831, 75840, 75842, 75860, 75870, 75872, and 75880.
- Move CPT codes 75960, 75961, 75964, 75968, 75970, 75978, 75992, and 75995 from APC 0279 to APC 0280.

We propose to accept the Panel's recommendations. We note that, as proposed, APC 0279 violates the 2 times rule because of the low cost data for CPT code 75660, Angiography, external carotid, unilateral selective, radiological supervision and interpretation. We believe that, for these procedures, these cost data are aberrant. This code is clinically similar to the other codes in APC 0279 and moving code 75660 to an APC with a lower weight could be an inappropriate APC assignment. Therefore, we believe that an exception to the 2 times rule is warranted.

APC 0300: Level I Radiation Therapy

APC 0302: Level III Radiation Therapy

We presented this APC to the Panel because we received comments that the assignment of CPT code 61793, Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator), one or more sessions, to APC 0302 would result in inappropriate payment of this service. Many commenters wrote that stereotactic radiosurgery and intensity modulated radiation therapy (IMRT) required significantly more staff time, treatment time, and resources than other types of radiation therapy. Other commenters disagreed with our decision, effective January 1, 2001, to discontinue recognizing CPT code 61793, and to create two HCPCS level 2 codes, G0173, Stereotactic radiosurgery, complete course of therapy in one session, and G0174 Intensity modulated radiation therapy (IMRT) plan, per session, to report both stereotactic radiosurgery and IMRT.

We reported to the Panel that the APC assignment of these G codes and their payment rate was based on our understanding that stereotactic radiosurgery was generally performed on an inpatient basis and delivered a complete course of treatment in a single session, while IMRT was performed on an outpatient basis and required several sessions to deliver a complete course of treatment. We also explained to the Panel that it was our understanding that multiple CPT codes were billed for each session of stereotactic radiosurgery and IMRT. Therefore, we believed that the payment for APC 0302 was only a fraction of the total payment a hospital received for performing stereotactic radiosurgery or IMRT on an outpatient basis.

Radiosurgery equipment manufacturers, physician groups, and patient advocacy groups have both submitted comments to us and provided testimony to the APC Panel on these issues. These comments have convinced us that we did not clearly understand either the relationship of IMRT to stereotactic radiosurgery or the various types of equipment used to perform these services.

We are proposing to set forth a proposed new coding structure that more accurately reflects the clinical use of these services and the resources required to perform them. Our understanding of these services, based on review of the comments, the testimony before the Panel, the Panel discussion and recommendations, and meetings with knowledgeable stakeholders, is described below.

Recent developments in the field of radiation oncology include the ability to deliver high doses of radiation to abnormal tissues (e.g., tumors) while minimizing delivery of radiation to adjacent normal tissues. Collectively, these procedures are called stereotactic radiosurgery and IMRT.

Clinically, there are essentially two services required to deliver stereotactic radiosurgery and IMRT. First, there is ''treatment planning,'' which includes such activities as determining the location of all normal and abnormal tissues, determining the amount of radiation to be delivered to the abnormal tissue, determining the dose tolerances of normal tissues, and determining how to deliver the required dose to abnormal tissue while delivering a dose to adjacent normal tissues within their range of tolerance. These activities include the ability to manufacture various treatment devices for protection of normal tissue as well as the ability to ensure that the plan will deliver the intended doses to normal and abnormal tissue by simulating the treatment. Second, there is ''treatment delivery,'' which is the actual delivery of radiation to the patient in accordance with the treatment plan. Treatment delivery includes such activities as adjusting the collimator (a device that filters the radiation beams), doing setup and verification images, treating one or more areas, and performing quality control.

Treatment planning requires specialized equipment including a duplicate of the actual equipment used to deliver the treatment, the ability to perform a CT scan, various disposable supplies, and involvement of various staff such as the physician, the physicist, the dosimetrist, and the radiation technologist. Treatment delivery requires specialized equipment to deliver the treatment and the involvement of the radiation technologist. The physician and physicist provide general oversight of this process.

Although there are several types of equipment, produced by several manufacturers, used to accomplish this treatment, it is the consensus of the commenters and the Panel that the most useful way to categorize stereotactic radiosurgery and IMRT is by the source of radiation used for the treatment and

not by the type of equipment used. One reason for this is that the clinical indications for stereotactic radiosurgery and IMRT overlap. Therefore, a single disease process can be treated by either modality but the cost of treatment varies by source of radiation used for the treatment. Second, while both stereotactic radiosurgery and IMRT can deliver a complete course of treatment in either one or multiple sessions, the cost of treatment delivery per session is relatively fixed, and is closely related to the source of radiation used for the treatment. Therefore, we believe that appropriate APC assignment and payment can be made by creating a small number of HCPCS codes to describe these services. The proposed codes are as follows:

- GXXX1 Multi-source photon stereotactic radiosurgery (Cobalt 60 multi-source converging beams) plan, including dose volume histograms for target and critical structure tolerances, plan optimization performed for highly conformal distributions, plan positional accuracy and dose verification, all lesions treated, per course of treatment.
- GXXX2 Multi-source photon stereotactic radiosurgery, delivery including collimator changes and custom plugging, complete course of treatment, per lesion.
- G0174 Intensity modulated radiation therapy (IMRT) delivery to one or more treatment areas, multiple couch angles/fields/arcs custom collimated pencil-beams with treatment setup and verification images, complete course of therapy requiring more than one session, per session.
- G0178 Intensity modulated radiation therapy (IMRT) plan, including dose volume histograms for target and critical structure partial tolerances, inverse plan optimization performed for highly conformal distributions, plan positional accuracy and dose verification, per course of treatment.

We propose that HCPCS codes GXXX1, G0174, and G0178 have status indicators of S, while GXXX2 have a status indicator of T. We believe these are the correct status indicators because G0178 has a ''per session'' designation, while GXXX2 has a ''per lesion'' designation. Furthermore, it is our understanding that GXXX1 would not be billed on a ''per lesion'' basis as the planning process would take into account all lesions being treated and it would be extremely difficult to determine resource utilization for planning on a ''per lesion'' basis. Because the costs of performing GXXX1 will vary based on the number of lesions treated, payment would reflect a weighted average.

It is our understanding that single-source photon stereotactic radiosurgery (or LINAC) planning and delivery are similar to IMRT planning and delivery in terms of clinical use and resource requirements. Therefore, we propose to require coding for single-source photon stereotactic radiosurgery under HCPCS codes G0174 and G0178.

Further, we are aware that the AMA is establishing codes for IMRT planning and treatment delivery for 2002 and we propose to retire G0174 and G0178 (with the usual 90-day phase out) and recognize the applicable CPT codes when they are established in January 2002.

We believe that all activities required to perform stereotactic radiosurgery and IMRT are included in the codes described above. In order to avoid confusion and to optimize tracking of these services in terms of both utilization and cost, we propose to discontinue the use of any other radiation therapy codes for activities involved with planning and delivery of stereotactic radiosurgery and IMRT for purposes of hospital billing in OPPS. Thus, we would continue to not recognize CPT code 61793 for hospital billing purposes.

We believe the coding requirements set forth above not only simplify the reporting process for hospitals, but appropriately recognize the clinical practice and resource requirements for stereotactic radiosurgery and IMRT.

We seek comments on our proposal, including the code titles, descriptors, and coding requirements discussed above. We also request information regarding appropriate APC assignment and payment rates to inform our decision-making. In particular, we would like information regarding the costs of treatment delivery including any differences between the cost of a complete treatment in single versus multiple sessions.

We also note that several commenters requested placement of the stereotactic delivery codes in surgical APCs and we request clarification and support for these comments within the context of our coding proposal. Specifically, we are concerned that appropriate payment be made for GXXX2, which has a ''per lesion'' descriptor.

We believe that while the APC Panel did not make any specific recommendations regarding these codes, the concerns expressed by the Panel are addressed by our proposal.

APC 0311: Radiation Physics Services

APC 0312: Radio Element Application

APC 0313: Brachytherapy

We presented APC 0311 to the Panel because we believed our cost data for CPT codes 77336, Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy; 77370, Special medical radiation physics consultation; and 77399, Unlisted procedure, medical radiation physics, dosimetry, and treatment devices, and special services, were inaccurate. We were concerned that these procedures, particularly code 77370, were not being paid appropriately in APC 0311.

Presenters pointed out that, as with all radiation oncology services, the usual practice is to bill multiple CPT codes on the same date of service. Therefore, single claims were likely to be inaccurate bills and did not represent the true costs of the procedure. For this reason, presenters believe that using single claims to set payment rates for radiation oncology procedures was inappropriate and that we needed to develop a methodology that allowed the use of multiple claims data to set payment rates for these services.

With regard to radiation physics consultation, presenters stated that the staff costs associated with CPT code 77370 were significantly greater than the costs of CPT codes 77336 and 77399. Therefore, they recommended that CPT codes 77336 and 77399 be moved from APC 0311 to APC 0304, Level I Therapeutic Radiation Treatment Preparation, and CPT code 77370 be moved from APC 0311 to APC 0305, Level II Therapeutic Radiation Treatment Preparation. The Panel agreed with this recommendation and we propose to accept the Panel's recommendation. We also agree that we should review the use of single claims to set payment rates for radiation oncology services. We plan to present this issue again at the 2002 Panel meeting.

We presented APCs 0312 and 0313 to the Panel because commenters were concerned that the payment rates were too low for the procedures assigned to the APCs and that there were insufficient data to set payment rates for these APCs. The Panel agreed that the issue regarding the use of single claim data affected the payment rates for these services. However, there were insufficient data for the Panel to make

any recommendations regarding these APCs. The Panel did request to look at the issue of radiation oncology at its 2002 meeting.

Therefore, we are proposing to make no changes to APCs 0312 and 0313 but will address radiation oncology issues at the Panel's 2002 meeting. We note that our updated claims data show very few single claims for procedures in these APCs. However, moving any of these procedures into other radiation oncology APCs would lower their payment rates.

APC 0371: Allergy Injections

We presented this APC to the Panel because it violates the 2 times rule. The median costs for CPT codes 95115, Professional Services for allergen immunotherapy not including provision of allergenic extracts; single injection, and 95117, Professional Services for allergen immunotherapy not including provision of allergenic extracts; two or more injections, were lower than the median costs for the other services in this APC.

The Panel agreed that because codes 95115 and 95117 included administration of an injection only, the resource utilization for these services was lower than for the other services. The other services involve preparation of antigen and require more staff time and hospital resources to perform.

In order to create clinical and resource homogeneity, the Panel recommended that we create a new APC for codes 95115 and 95117 and that we leave the other services in APC 0371. We propose to accept the Panel recommendation and create a new APC 0353, Level II Allergy Injections, and revise the title of APC 0371 to Level I Allergy Injections.

Observation Services

See the discussion on observation services in section II.C.4 of this preamble for a summary of the Panel discussion and recommendations and our proposal.

Inpatient Procedure List

See the discussion of the inpatient procedures list in section II.C.5 of this preamble for a summary of the Panel discussion and recommendations and our proposal.

B. Additional APC Changes Resulting from BIPA Provisions

1. Coverage of Glaucoma Screening

Section 102 of the BIPA amended section 1861(s)(2) of the Act to provide payment for glaucoma screening for eligible Medicare beneficiaries, specifically, those with diabetes mellitus or a family history of glaucoma, and certain other individuals found to be at high risk for glaucoma as specified by our rulemaking. The implementation of this provision is discussed in detail in a separate proposed rule concerning the revisions in the physician payment policy for CY 2002.

In order to implement section 102 of BIPA, we have established two new HCPCS codes for glaucoma screening:

G0117—Glaucoma screening for high risk patients furnished by an ophthalmologist or optometrist.

G0118—Glaucoma screening for high risk patients furnished under the direct supervision of an ophthalmologist or optometrist.

We are proposing to assign the glaucoma screening codes to APC 0230, Level I Eye Tests. We further propose to instruct our fiscal intermediaries to make payment for glaucoma screening only if it is the sole ophthalmologic service for which the hospital submits a bill for a visit. That is, the services included in glaucoma screening (a dilated eye examination with an intraocular pressure measurement and direct opthalmoscopy or slit-lamp biomicroscopy) would generally be performed during the delivery of another opthalmologic service that is furnished on the same day. If the beneficiary receives only a screening service, however, we would pay for it under APC 0230.

2. APCs for Contrast Enhanced Diagnostic Procedures

Section 430 of the BIPA amended section 1833(t)(2) of the Act to require the Secretary to create additional APC groups to classify procedures that utilize contrast agents separately from those that do not, effective for items and services furnished on or after July 1, 2001. On June 1, 2001, we issued a Program Memorandum, Transmittal A–01–73, in which we made numerous coding and grouping changes to implement this provision. (This transmittal can be found at www.hcfa.gov/pubforms/transmit/AO173.pdf) We removed the radiological procedures whose descriptors included either ''without contrast material'' or ''without contrast material followed by contrast material'' from APC groups 0282, Level I, Computerized Axial Tomography; APC 0283, Level II, Computerized Axial Tomography; and APC 0284, Magnetic Resonance Imaging. As a result, APCs 0283 and 0284 now include only imaging procedures that are performed with contrast materials. Additionally, reconfigured APC 0282 no longer includes radiological procedures that use contrast agents.

Effective for items or services furnished on or after July 1, 2001, we created six new APC groups for the procedures removed from APCs 0282, 0283, and 0284, as shown below. (Effective October 1, 2001, we will eliminate APC 0338. Refer to Transmittal A–01–73 for a detailed description of this change.) For services furnished on or after July 1, 2001 and before January 1, 2002, the payment rates for the new imaging APCs are the same as those associated with the APCs from which the procedures were moved. In this proposed rule, the weights for the new APCs are recalibrated based on the data we are using to set the weights for 2002.

TABLE 1.—APC GROUPS RECONFIGURED TO SEPARATE IMAGING PROCEDURES THAT USE CONTRAST MATERIAL FROM PROCEDURES THAT DO NOT USE CONTRAST MATERIAL

APC	SI	APC title
0282	S	Miscellaneous Computerized Axial Tomography.
0283	S	Computerized Axial Tomography with Contrast.
0284	S	Magnetic Resonance Imaging and Angiography with Contrast.
0332	S	Computerized Axial Tomography w/o Contrast.
0333	S	CT Angio and Computerized Axial Tomography w/o Contrast followed by with Contrast.
0335	S	Magnetic Resonance Imaging, Temporomandibular Joint.
0336	S	Magnetic Resonance Angiography and Imaging without Contrast.
0337	S	Magnetic Resonance Imaging and Angiography w/o Contrast followed by with Contrast.
0338	S	Magnetic Resonance Angiography, Chest and Abdomen with or w/o Contrast.

The HCPCS codes that are reassigned to the new imaging APCs in this proposed rule are as follows:

APC	HCPCS	SI	Short descriptor
0282	76370	S	CAT scan for therapy guide.
	76375	S	3d/holograph reconstr add-on.
	76380	S	CAT scan for follow-up study.
	G0131	S	Ct scan, bone density study.
	G0132	S	Ct scan, bone density study.
0283	70460	S	Ct head/brain w/dye.
	70481	S	Ct orbit/ear/fossa w/dye.
	70487	S	Ct maxillofacial w/dye.
	70491	S	Ct soft tissue neck w/dye.
	71260	S	Ct thorax w/dye.
	72126	S	Ct neck spine w/dye.
	72129	S	Ct chest spine w/dye.
	72132	S	Ct lumbar spine w/dye.
	72193	S	Ct pelvis w/dye.
	73201	S	Ct upper extremity w/dye.
	73701	S	Ct lower extremity w/dye.
	74160	S	Ct abdomen w/dye.
	76355	S	CAT scan for localization.
	76360	S	CAT scan for needle biopsy.
0284	70542	S	MRI orbit/face/neck w/dye.
	70545	S	Mr angiography head w/dye.
	70548	S	Mr angiography neck w/dye.
	70552	S	MRI brain w/dye.
	71551	S	MRI chest w/dye.
	72142	S	MRI neck spine w/dye.
	72147	S	MRI chest spine w/dye.
	72149	S	MRI lumbar spine w/dye.
	72196	S	MRI pelvis w/dye.
	73219	S	MRI upper extremity w/dye.
	73222	S	MRI joint upr extrem w/dye.
	73719	S	MRI lower extremity w/dye.
	73722	S	MRI joint of lwr extr w/dye.
	74182	S	MRI abdomen w/dye.
	75553	S	Heart MRI for morph w/dye.
	C8900	S	MRA w/cont, abd.
	C8903	S	MRI w/cont, breast, uni.
	C8906	S	MRI w/cont, breast, bi.
	C8909	S	MRA w/cont, chest.
	C8912	S	MRA w/cont, lwr ext.
0332	70450	S	CAT scan of head or brain.
	70480	S	Ct orbit/ear/fossa w/o dye.
	70486	S	Ct maxillofacial w/o dye.
	70490	S	Ct soft tissue neck w/o dye.
	71250	S	Ct thorax w/o dye.
	72125	S	Ct neck spine w/o dye.
	72128	S	Ct chest spine w/o dye.
	72131	S	Ct lumbar spine w/o dye.
	72192	S	Ct pelvis w/o dye.
	73200	S	Ct upper extremity w/o dye.
	73700	S	Ct lower extremity w/o dye.
	74150	S	Ct abdomen w/o dye.
0333	70470	S	Ct head/brain w/o&w dye.
	70482	S	Ct orbit/ear/fossa w/o&w dye.
	70488	S	Ct maxillofacial w/o&w dye.
	70492	S	Ct sft tsue nck w/o & w/dye.
	70496	S	Ct angiography, head.
	70498	S	Ct angiography, neck.
	71270	S	Ct thorax w/o&w dye.
	71275	S	Ct angiography, chest.
	72127	S	Ct neck spine w/o&w dye.
	72130	S	Ct chest spine w/o&w dye.
	72133	S	Ct lumbar spine w/o&w dye.
	72191	S	Ct angiograph pelv w/o&w dye.
	72194	S	Ct pelvis w/o&w dye.
	73202	S	Ct uppr extremity w/o&w dye.
	73206	S	Ct angio upr extrm w/o&w dye.
	73702	S	Ct lwr extremity w/o&w dye.
	73706	S	Ct angio lwr extr w/o&w dye.
	74170	S	Ct abdomen w/o&w dye.
	74175	S	Ct angio abdom w/o&w dye.
	75635	S	Ct angio abdominal arteries.
0335	70336	S	Magnetic image, jaw joint.
	75554	S	Cardiac mri/function.
	75555	S	Cardiac mri/limited study.

APC	HCPCS	SI	Short descriptor
	76390	S	Mr spectroscopy.
	76400	S	Magnetic image, bone marrow.
0336	70540	S	MRI orbit/face/neck w/o dye.
	70544	S	Mr angiography head w/o dye.
	70547	S	Mr angiography neck w/o dye.
	70551	S	MRI brain w/o dye.
	71550	S	MRI chest w/o dye.
	72141	S	MRI neck spine w/o dye.
	72146	S	MRI chest spine w/o dye.
	72148	S	MRI lumbar spine w/o dye.
	72195	S	MRI pelvis w/o dye.
	73218	S	MRI upper extremity w/o dye.
	73221	S	MRI joint upr extrem w/o dye.
	73718	S	MRI lower extremity w/o dye.
	73721	S	MRI joint of lwr extre w/o dye.
	74181	S	MRI abdomen w/o dye.
	75552	S	Heart MRI for morph w/o dye.
	C8901	S	MRA w/o cont, abd.
	C8904	S	MRI w/o cont, breast, uni.
	C8910	S	MRA w/o cont, chest.
	C8913	S	MRA w/o cont, lwr ext.
0337	70543	S	MRI orbt/fac/nck w/o&w dye.
	70546	S	Mr angiograph head w/o&w dye.
	70549	S	Mr angiograph neck w/o&w dye.
	70553	S	MRI brain w/o&w dye.
	71552	S	MRI chest w/o&w dye.
	72156	S	MRI neck spine w/o&w dye.
	72157	S	MRI chest spine w/o&w dye.
	72158	S	MRI lumbar spine w/o&w dye.
	72197	S	MRI pelvis w/o&w dye.
	73220	S	MRI uppr extremity w/o&w dye.
	73223	S	MRI joint upr extr w/o&w dye.
	73720	S	MRI lwr extremity w/o&w dye.
	73723	S	MRI joint lwr extr w/o&w dye.
	74183	S	MRI abdomen w/o&w dye.
	C8902	S	MRA w/o fol w/cont, abd.
	C8905	S	MRI w/o fol w/cont, brst, uni.
	C8908	S	MRI w/o fol w/cont, breast, bi.
	C8911	S	MRA w/o fol w/cont, chest.
	C8914	S	MRA w/o fol w/cont, lwr ext.

Refer to Addendum A or Addendum B for the updated weights, payment rates, national unadjusted copayment, and minimum unadjusted copayment that we are proposing for all of the procedures listed above.

C. Other Changes Affecting the APCs

1. Changes in Revenue Code Packaging

In the April 7, 2000 final rule, we described how, in calculating the per procedure and per visit costs to determine the median cost of an APC (and therefore its relative weight), we used the charges billed using the revenue codes that contained items that were integral to performing the procedure or visit (65 FR 18483). For example, in calculating the cost of a surgical procedure, we included charges for revenue codes such as operating room, treatment rooms, recovery, observation, medical and surgical supplies, pharmacy, anesthesia, casts and splints, and donor tissue, bone, and organ. For medical visit costs, we included charges for items such as medical and surgical supplies, drugs, and observation. The complete list of the revenue centers by type of APC group was printed in the April 7, 2000 rule (65 FR 18484).

In the November 13, 2000 interim final rule, we made some changes to the list of revenue codes to reflect the charges associated with implantable devices (65 FR 67806 and 67825). As we stated in that rule, charges included in revenue codes 274 (prosthetic/orthotic devices), 275 (pacemaker), and 278 (other implants) were not included in the initial APC payment rates because, before enactment of BBRA, we were proposing to pay these devices outside of the OPPS, and, after the enactment of the BBRA, it was not feasible to revise our database to include these revenue codes in developing the April 7, 2000 final rule. As discussed in the November 13, 2000 interim final rule, we were later able to incorporate these revenue codes in our database, and effective January 1, 2001, we updated the APC payment rates to reflect inclusion of this information.

We have continued to review and revise the list of revenue codes to be included in the database and we are proposing several changes to the list of revenue codes that are packaged with the costs used to calculate the proposed APC rates. Some of these changes reflect the addition of revenue codes and others are a further refinement of our methodology. The following are the specific changes we are proposing to make:

- Package additional revenue centers that may be used to bill for implantable devices (including durable medical equipment (DME) and brachytherapy seeds) with surgical procedures. These additional centers are revenue codes 280 (oncology), 289 (other oncology), 290 (DME), and 624 (investigational devices).
- Package revenue codes 280, 289, and 624 with other diagnostic and radiology services.
- Package the revenue codes for medical social services, 560 (medical social services) and 569 (other medical social services). These services are not

paid separately in the hospital outpatient setting but often constitute discharge-planning services if provided with an outpatient service.

• Package revenue code 637 (self-administered drug (insulin administered in an emergency diabetic coma)) with medical visits. Although this is a self-administrable drug, it is covered when administered as described.

• Remove revenue code 723 (circumcision) from the list of packaged revenue codes because circumcision is a payable procedure under OPPS and should not be packaged.

• Package revenue code 942 (education/training) with medical visits and the category of ''All Other APC Groups.'' Patient training and education are generally not paid as a separate service under Medicare, but may be included as part of an otherwise payable service such as a medical visit. We believe that training and education services generally occur as part of a medical visit or psychiatric service.

• Remove the revenue codes in the range of 890 through 899 (donor bank), as these are no longer valid revenue codes.

2. Special Revenue Code Packaging for Specific Types of Procedures

We are proposing that the same packaging used for surgical procedures be used for corneal tissue implant procedures in APC 0244, Corneal Transplant, except that organ acquisition revenue codes and the revenue codes used to bill implantable devices are not packaged with corneal implants.

There are certain other diagnostic procedures with CPT codes that are similar to surgical procedures. The cost of these procedures (HCPCS codes 92980–92996, 93501–93505, and 93510–93536) reflects both the revenue code packaging for ambulatory surgical center (ASC) and other surgery, as well as the revenue code packaging for other diagnostic services.

A complete listing of the revenue codes that we are proposing in this rule and that we used for purposes of calculating median costs of services are shown below in Table 2.

Table 2.—Packaged Services by Revenue Code

Surgery

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
260 IV THERAPY, GENERAL CLASS
262 IV THERAPY/PHARMACY SERVICES
263 IV THERAPY/DRUG SUPPLY/DELIVERY
264 IV THERAPY/SUPPLIES
269 OTHER IV THERAPY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
274 PROSTHETIC/ORTHOTIC DEVICES
275 PACEMAKER DRUG
276 INTRAOCULAR LENS SOURCE DRUG
278 OTHER IMPLANTS
279 OTHER M&S SUPPLIES
280 ONCOLOGY
289 OTHER ONCOLOGY
290 DURABLE MEDICAL EQUIPMENT
370 ANESTHESIA
379 OTHER ANESTHESIA
390 BLOOD STORAGE AND PROCESSING
399 OTHER BLOOD STORAGE AND PROCESSING
560 MEDICAL SOCIAL SERVICES
569 OTHER MEDICAL SOCIAL SERVICES
624 INVESTIGATIONAL DEVICE (IDE)
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE
632 MULTIPLE
633 RESTRICTIVE PRESCRIPTION
700 CAST ROOM
709 OTHER CAST ROOM
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
720 LABOR ROOM
721 LABOR
762 OBSERVATION ROOM
810 ORGAN AQUISITION
819 OTHER ORGAN ACQUISITION

Medical Visit

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
279 OTHER M&S SUPPLIES
560 MEDICAL SOCIAL SERVICES
569 OTHER MEDICAL SOCIAL SERVICES
630 DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
637 SELF-ADMINISTERED DRUG (INSULIN ADMIN. IN EMERGENCY DIABETIC COMA)
700 CAST ROOM
709 OTHER CAST ROOM
762 OBSERVATION ROOM
942 EDUCATION/TRAINING

Other Diagnostic

254 PHARMACY INCIDENT TO OTHER DIAGNOSTIC
280 ONCOLOGY
289 OTHER ONCOLOGY
372 ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC
560 MEDICAL SOCIAL SERVICES
569 OTHER MEDICAL SOCIAL SERVICES
622 SUPPLIES INCIDENT TO OTHER DIAGNOSTIC
624 INVESTIGATIONAL DEVICE (IDE)
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
762 OBSERVATION ROOM

Radiology

255 PHARMACY INCIDENT TO RADIOLOGY
280 ONCOLOGY
289 OTHER ONCOLOGY
371 ANESTHESIA INCIDENT TO RADIOLOGY
560 MEDICAL SOCIAL SERVICES
710 RECOVERY ROOM
719 OTHER RECOVERY ROOM
569 OTHER MEDICAL SOCIAL SERVICES
621 SUPPLIES INCIDENT TO RADIOLOGY
624 INVESTIGATIONAL DEVICE (IDE)
762 OBSERVATION ROOM

All Other APC Groups

250 PHARMACY
251 GENERIC
252 NONGENERIC
257 NONPRESCRIPTION DRUGS
258 IV SOLUTIONS
259 OTHER PHARMACY
260 IV THERAPY, GENERAL CLASS
262 IV THERAPY PHARMACY SERVICES
263 IV THERAPY/DRUG/SUPPLY/DELIVERY
264 IV THERAPY SUPPLIES
269 OTHER IV THERAPY
270 M&S SUPPLIES
271 NONSTERILE SUPPLIES
272 STERILE SUPPLIES
279 OTHER M&S SUPPLIES
560 MEDICAL SOCIAL SERVICES
569 OTHER MEDICAL SOCIAL SERVICES
630 DRUG REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631 SINGLE SOURCE DRUG
632 MULTIPLE SOURCE DRUG
633 RESTRICTIVE PRESCRIPTION
762 OBSERVATION ROOM
942 EDUCATION/TRAINING

3. Limit on Variation of Costs of Services Classified Within a Group

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost item or service within a group is more than 2 times greater than the lowest cost item or service within the same group, but the Secretary may make exceptions to this limit on the variation of costs within each group in unusual cases such as low volume items and services. No exception may be made, however, in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act.

Based on the proposed APC changes discussed above in this section of this preamble and the use of more current data to calculate the median cost of procedures classified to APCs, we reviewed all the APCs to determine which of them would not meet the 2 times limit. We use the following

criteria when deciding whether to make exceptions to the 2 times rule for affected APCs:

- Resource homogeneity.
- Clinical homogeneity.
- Hospital concentration.
- Frequency of service (volume).
- Opportunity for upcoding and code fragmentation.

For a detailed discussion of these criteria, refer to the April 7, 2000 final rule (65 FR 18457).

The following list contains APCs that we propose to except from the 2 times rule based on the criteria cited above. In cases in which compliance with the 2 times rule appeared to conflict with a recommendation of the APC Advisory Panel, we generally accepted the Panel recommendation. This was because Panel recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the data used to determine payment rates.

0001 Photochemotherapy
0041 Arthroscopy
0044 Closed Treatment Fracture/Dislocation Except Finger/Toe/Trunk
0047 Arthroplasty without Prosthesis
0058 Level I Strapping and Cast Application
0077 Level I Pulmonary Treatment
0093 Vascular Repair/Fistula Construction
0096 Noninvasive Vascular Studies
0097 Cardiac Monitoring for 30 days
0115 Cannula/Access Device Procedures
0121 Level I Tube Changes and Repositioning
0140 Esophageal Dilation without Endoscopy
0147 Level II Sigmoidoscopy
0164 Level I Urinary and Anal Procedures
0165 Level II Urinary and Anal Procedures
0182 Insertion of Penile Prosthesis
0198 Pregnancy and Neonatal Care Procedures
0203 Level V Nerve Injections
0204 Level VI Nerve Injections
0207 Level IV Nerve Injections
0213 Extended EEG Studies and Sleep Studies
0215 Level I Nerve and Muscle Tests
0231 Level II Eye Tests
0238 Level I Repair and Plastic Eye Procedures
0251 Level I ENT Procedures
0260 Level I Plain Film Except Teeth
0265 Level I Diagnostic Ultrasound Except Vascular
0279 Level I Angiography and Venography except Extremity
0285 Positron Emission Tomography (PET)
0305 Level II Therapeutic Radiation Preparation
0322 Brief Individual Psychotherapy
0345 Level I Transfusion Lab Procedures
0349 Miscellaneous Lab Procedures
0354 Administration of Influenza/Pneumonia Vaccine
0356 Level II Immunizations
0363 Otorhinolaryngologic Function Tests
0364 Level I Audiometry
0373 Neuropsychological Testing
0602 High Level Clinic Visits
0694 Level III Excision/Biopsy
0697 Level II Transesophageal Procedures

4. Observation Services

Observation services have a long intertwined clinical and payment history. For many years, beneficiaries have been placed in ''observation status'' in order to receive treatment or be monitored before making a decision concerning their next placement (that is, admit to the hospital or discharge to home). This occurs most frequently after surgery or a visit to the emergency department. Typically, beneficiaries placed in observation have failed to respond to initial emergency department treatment for their condition (for example, exacerbation of asthma), have symptoms placing them at significant risk for mortality (for example, chest pains with the possibility of myocardial infarction), or have received anesthesia for a surgical procedure and need to be monitored postoperatively. Clinically, most beneficiaries do not require more than 24 hours of observation before a decision concerning admission or discharge can be made. Therefore, it is rare that it is clinically justifiable to keep a patient in observation for more than 24 to 48 hours. The location where observation services are provided is facility-specific, and sometimes individual-specific. It is not uncommon for beneficiaries to be observed in the emergency department, in a designated unit near the emergency department, or in an intensive care or other unit in the facility.

After implementation of the Medicare hospital inpatient PPS in 1983, peer review organizations (PROs) began to review inpatient admissions to determine whether the admission and the length of stay were appropriate. Because ''observation care'' is considered to be an outpatient service, facilities began using ''observation'' as an administrative mechanism to care for beneficiaries who, if admitted as inpatients, might have their admission questioned by the PRO. Moreover, before the implementation of the OPPS, the payment for observation care was on a reasonable cost basis, which frequently gave hospitals a financial incentive to keep beneficiaries in ''observation status'' even though they were clinically being treated as inpatients. Occasionally, beneficiaries were kept in observation for days and weeks resulting in both excessive payments from the Medicare program and excessive copayments from the beneficiary. In response to this practice, Medicare revised its manuals in November 1996, limiting covered observation services to no more than 48 hours (section 456 of the Hospital Manual and section 3663 of the Intermediary Manual).

The costs for all observation services provided in the outpatient setting, even those provided in excess of 48 hours, were included in the initial APC payment rates. Currently, observation services are not paid separately, that is, they are not assigned to a separate APC. Instead, costs for observation services are packaged into payments for services with which the observation was billed in 1996. Observation was most frequently billed with emergency department visits, clinic visits, and surgical procedures. The payments for all APCs include the costs of observation to the extent that it was billed in 1996. In the 1996 data, we identified and packaged a total of $392 million from revenue codes 760, 761, 762, and 769, which represented observation services.

In the April 7, 2000 final rule (65 FR 18448), we responded to numerous comments concerning observation services. Even though commenters acknowledged that being paid separately for observation services following a surgical procedure was unnecessary, many commenters requested that we pay separately for observation services following emergency department visits. Among those commenters requesting separate payment for observation, some requested separate payment for specific medical conditions, and others requested payment for all medical conditions. Some commenters provided articles and books containing clinical research on the value and cost effectiveness of observation for certain patients. Although we did not decide to create a separate APC for observation services, we did include this topic in the agenda for our APC Panel, which met from February 27 to March 1, 2001. While individual Panel members agreed that use of observation services had been abused in the past by hospitals seeking to maximize payment, the Panel also agreed that observation services following clinic and emergency room visits should be paid separately. In addition, the Panel believed that observation following surgery should be packaged into the payment for the surgical procedure. The Panel did not dispute that the vast majority of patients are admitted to the hospital or discharged home from observation in less than 24 hours, and Panel members judged that a rule limiting separate payment to 24 hours of observation

would be reasonable. The Panel also noted that because Medicare currently allows hospitals to report observation services up to 48 hours, hospital staff and coders would have to be educated were we to change the current standard.

Since the Panel meeting, we have reviewed all comments we have received on this issue. In determining whether we should pay separately for observation services, our primary concern is to ensure that Medicare beneficiaries have access to medically necessary observation care. We also want to ensure that payment be made only for beneficiaries actually receiving observation care, and that payment be restricted to clinically appropriate observation care. We paid particular attention to the Qualcare criteria (severity of illness and intensity of service criteria used by some insurance plans to determine whether it is appropriate for a patient to receive observation care) for observation services and to those comments providing medical evidence on the value and cost effectiveness of observation care. We also carefully considered logistical and administrative issues related to delivering observation care such as whether payment for emergency services should be bundled into observation services, the potential for overuse of the services, and the need for treatment guidelines. We also considered how to most appropriately define the starting time, discharge time, and minimum length of stay for observation care.

Finally, in considering whether to make a separate payment for observation care, we had to balance the issues of access, medical necessity, potential for abuse, and need to ensure appropriate payment. As a threshold requirement for candidate medical conditions, we sought published criteria regarding the following:

- Risk stratification of patients to determine which patient sub-populations benefit from observation care.
- Which patients should be admitted to observation.
- Which patients should be discharged home from observation.
- When patients should be admitted to the hospital from observation.
- Patient management.

We found that these criteria were met for chest pain, asthma, and congestive heart failure.

The fulfillment of these criteria ensured that, for these conditions, observation care avoided significant morbidity and mortality from inappropriate discharge to home while at the same time avoiding unnecessary inpatient admissions. For example, the use of observation for selected patients with asthma and congestive heart failure can reduce the rate of return emergency visits and subsequent admission. The literature clearly shows that for these patients, observation care requires prolonged physiologic monitoring and intensive treatment to result in the beneficial outcomes.

After careful consideration, we are proposing—

- To continue to package observation services into surgical procedures; and
- To create a single APC, APC 0339, Observation, to make separate payment for observation services for three medical conditions, chest pain, asthma, and congestive heart failure, when certain criteria (as described below) are met.

We are further proposing to instruct hospitals that payment under APC 0339 for observation services would be subject to the following billing requirements and conditions:

- An emergency department visit (APC 0610, 0611, or 0612) or a clinic visit (APC 0600, 0601, or 0602) is billed in conjunction with each bill for observation services.
- Observation care is billed hourly for a minimum of 8 hours up to a maximum of 48 hours. We would not pay separately for any hours a beneficiary spends in observation over 24 hours, but all costs beyond 24 hours would be packaged into the APC payment for observation services.
- Observation time begins at the clock time appearing on the nurse's observation admission note. (We note that this coincides with the initiation of observation care or with the time of the patient's arrival in the observation unit.)
- Observation time ends at the clock time documented in the physician's discharge orders, or, in the absence of such a documented time, the clock time when the nurse or other appropriate person signs off on the physician's discharge order. (This time coincides with the end of the patient's period of monitoring or treatment in observation.)
- The beneficiary is under the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes, timed, written, and signed by the physician.
- The medical record includes documentation that the physician used risk stratification criteria to determine that the beneficiary would benefit from observation care. (These criteria may be either published generally accepted medical standards or established hospital-specific standards.)
- The hospital furnishes certain other diagnostic services along with observation services to ensure that separate payment is made only for those beneficiaries truly requiring observation care. We believe that these tests are typically performed on beneficiaries requiring observation care for the three specified conditions and they are medically necessary to determine whether a beneficiary will benefit from being admitted to observation care and the appropriate disposition of a patient in observation care. The diagnostic tests are as follows:
- For chest pain, at least two sets of cardiac enzymes and two sequential electrocardiograms.
- For asthma, a peak expiratory flow rate (PEFR) (CPT code 94010) and nebulizer treatments.
- For congestive heart failure, a chest x-ray, an electrocardiogram, and pulse oximetry.

We are proposing to make payment for APC 0339 only if the tests described above are billed on the same claim as the observation service.

(We are not proposing to require telemetry and other ongoing monitoring services as criteria to make separate payment for observation services. Although these services are often medically necessary to ensure prompt diagnosis of cardiac arrhythmias and other disorders, we do not believe they are necessary to support separate payment for observation services.)

We propose to require that, in order to receive payment for APC 0339, the hospital must include one of the ICD–9–CM diagnosis codes listed below in the diagnosis field of the bill. We propose the following diagnosis codes to indicate a symptom or condition that would require observation:

For Chest Pain

411.1 Intermediate coronary syndrome
411.81 Coronary occlusion without myocardial infarction
411.0 Postmyocardial infarction syndrome
411.89 Other acute ischemic heart disease
413.0 Angina decubitus
413.1 Prinzmetal angina
413.9 Other and unspecified angina pectoris
786.05 Shortness of breath
786.50 Chest pain, unspecified
786.51 Precordial pain
786.52 Painful respiration
786.59 Other chest pain

For Asthma

493.01 Extrinsic asthma with status asthmaticus
493.02 Extrinsic asthma with acute exacerbation

493.11 Intrinsic asthma with status asthmaticus
493.12 Intrinsic asthma with acute exacerbation
493.21 Chronic obstructive asthma with status asthmaticus
493.22 Chronic obstructive asthma with acute exacerbation
493.91 Asthma, unspecified with status asthmaticus
493.92 Asthma, unspecified with acute exacerbation

For Congestive Heart Failure

428.0 Congestive heart failure
428.1 Left heart failure
428.9 Heart failure, unspecified

We used the following process to identify the appropriate median cost for APC 0339. First, we identified in the 1999–2000 claims data all hospital outpatient claims for observation using revenue codes 760, 761, 762, and 769. We then selected the subset of these claims that were billed for patients with chest pain, asthma, and congestive heart failure. Because no standard method for coding these claims was in place in 1996, we identified all diagnosis codes that could reasonably have been used to classify beneficiaries as having chest pain, asthma, and congestive heart failure. We then verified that these beneficiaries received appropriate observation care for chest pain, asthma, or congestive heart failure by identifying the claims in which one or more of the tests identified above were performed. The median costs of these claims were used to establish the median costs of APC 0339.

We appreciate that there are other medical conditions for which selected beneficiaries may benefit from observation care and we are interested in comments on whether we should make separate payment for observation care for other conditions. We will consider medical research submitted to support the benefits of observation services for these conditions. This information will assist us in determining whether these other conditions meet the criteria we used to select the three conditions we have proposed to include in APC 0339.

5. List of Procedures That Will Be Paid Only as Inpatient Procedures

Before implementation of the OPPS, Medicare paid reasonable costs for services provided in the outpatient department. The claims submitted were subject to medical review by the fiscal intermediaries to determine the appropriateness of providing certain services in the outpatient setting. We did not specify in regulations those services that were appropriate to provide only in the inpatient setting and that, therefore, should be payable only when provided in that setting.

Section 1833(t)(1)(B)(i) of the Social Security Act gave the Secretary broad authority to determine the services to be covered and paid for under the OPPS. In the September 8, 1998 OPPS proposed rule, we defined a set of services that are typically provided only in an inpatient setting and, hence, would not be paid by Medicare under the OPPS. This set of services is referred to as the ''inpatient list.''

We received numerous comments on the inpatient list. In the April 7, 2000 final rule, we revised the proposed list by removing a number of services and we discussed in greater detail the criteria we will use to define which services will be included on the inpatient list (65 FR 18455). These are services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient.

After publication of the April 7 final rule, we received information from a number of groups demonstrating that certain services are routinely provided safely in the outpatient setting. As a result, in the November 13, 2000 interim final rule, we removed 44 procedures from the list (65 FR 67826). In that rule, we also stated that we would update the list at least quarterly to reflect advances in medical practice that permit procedures to be routinely performed in the outpatient setting. And, on June 1, 2001, we issued Program Memorandum A–01–73 in which we moved an additional 23 procedures from the inpatient list.

At its February 2001 meeting, the APC Advisory Panel discussed the existence of the inpatient list. The Advisory Panel generally favored its elimination. In this instance, we disagree with the position taken by the Panel. Rather, we propose to continue the current policy of reviewing the HCPCS codes on the inpatient list and eliminating procedures from the list if they can be appropriately performed on the Medicare population in the outpatient setting. Our medical and policy staff, supplemented as appropriate by the APC Advisory Panel, would review comments submitted by the public and consider advances in medical practice in making decisions to remove codes from the list. We would continue to use the following criteria, which we discussed in the April 7, 2000 final rule, when deciding to remove codes from the list:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes we have already moved off the inpatient list (for example, the radiologic part of an interventional cardiology procedure).

We would continue to update the list in response to comments as often as quarterly through program memoranda to reflect current advances in medical practice. We believe that the current list addresses the concerns of previous commenters and reflects a general consensus about those services that hospitals and physicians agree are not routinely performed in the outpatient setting. Therefore, at this time, we are proposing no further changes to the inpatient list, which is set forth in Addendum E to this proposed rule.

6. Additional New Technology APC Groups

In the April 7, 2000 final rule, we created 15 new technology APC groups to pay for new technologies that do not meet the statutory requirements for transitional pass-through payments and for which we have little or no data upon which to base assignment to an appropriate APC. APC groups 0970 through 0984 are the current new technology APCs. We currently assign services to a new technology APC for 2 to 3 years based solely on costs, without regard to clinical factors. This method of paying for new technologies allows us to gather data on their use for subsequent assignment to a clinically-based APC. Payment rates for the new technology APCs are based on the midpoint of ranges of possible costs.

After evaluating the costs of services in the new technology APCs, we are proposing that APC 0982, which covers a range of costs from $2500 to $3500, be split into two APCs, as follows: APC 0982, which would encompass services whose costs fall between $2500 and $3000, and APC 0983, which would encompass those services whose costs fall between $3000 and $3500. APC 0984 would then encompass services whose costs fall between $3500 and $5000 and we would create a new APC, 0985, for services whose costs fall between $5000 and $6000. We believe that subdividing the current range of costs within APC 0982 would allow us to pay more accurately for the services in that cost range.

In section VI.G of this preamble, we describe several modifications and refinements to the criteria and process

for assigning services to new technology APCs that we are proposing in this rule.

Table 3 below, lists all of the APC groups that we are proposing to change for 2002.

TABLE 3.—APC GROUPS PROPOSED TO BE CHANGED IN 2002

APC	Title	SI	APC panel	2 times	Other
0002	Fine needle Biopsy/Aspiration	T		X	
0004	Level I Needle Biopsy/Aspiration Except Bone Marrow	T		X	
0006	Level I Incision & Drainage	T		X	
0007	Level II Incision & Drainage	T		X	
0008	Level III Incision & Drainage	T		X	
0012	Level I Debridement & Destruction	T		X	
0013	Level II Debridement & Destruction	T		X	
0014	Level III Debridement and Destruction	T		X	
0015	Level IV Debridement & Destruction	T		X	
0016	Level V Debridement & Destruction	T	X	X	
0017	Level VI Debridement & Destruction	T	X	X	
0018	Biopsy of Skin/Puncture of Lesion	T		X	
0019	Level I Excision/Biopsy	T		X	
0020	Level II Excision/Biopsy	T		X	
0021	Level IV Excision/Biopsy	T		X	
0022	Level V Excision/Biopsy	T		X	
0026	Level III Skin Repair	T		X	
0027	Level IV Skin Repair	T		X	
0029	Level II Incision/Excision Breast	T		X	
0030	Level I Breast Reconstruction	T		X	
0032	Insertion of Central Venous/Arterial Catheter	T		X	
0035	Placement of Arterial/Central Venous Catheter	T		X	
0043	Closed Treatment Fracture Finger/Toe/Trunk	T		X	
0044	Closed Treatment Fracture/Dislocation except Finger/Toe/Trunk	T		X	
0045	Bone/Joint Manipulation Under Anesthesia	T		X	
0049	Level I Musculoskeletal Procedures Except Hand and Foot	T		X	
0050	Level II Musculoskeletal Procedures Except Hand and Foot	T		X	
0058	Level I Strapping and Cast Application	S		X	
0059	Level II Strapping and Cast Application	S		X	
0068	CPAP Initiation	S	X		
0069	Thoracoscopy	T		X	
0074	Level IV Endoscopy Upper Airway	T		X	
0075	Level V Endoscopy Upper Airway	T		X	
0076	Endoscopy Lower Airway	T		X	
0079	Ventilation Initiation and Management	S	X		
0082	Coronary Atherectomy	T		X	
0083	Coronary Angioplasty	T		X	
0087	Cardiac Electrophysiologic Recording/Mapping	S	X		
0088	Thrombectomy	T		X	
0093	Vascular Repair/Fistula Construction	T		X	
0094	Resuscitation and Cardioversion	S	X		
0097	Cardiac Monitoring for 30 days	T		X	
0102	Electronic Analysis of Pacemakers/other Devices	S	X		
0105	Revision/Removal of Pacemakers, AICD, or Vascular Device	T	X		
0111	Blood Product Exchange	S	X		
0112	Apheresis, Photopheresis, and Plasmapheresis	S	X		
0115	Cannula/Access Device Procedures	T		X	
0125	Refilling of Infusion Pump	T	X		
0130	Level I Laparoscopy	T		X	
0131	Level II Laparoscopy	T		X	
0148	Level I Anal/Rectal Procedure	T		X	
0149	Level III Anal/Rectal Procedure	T		X	
0150	Level IV Anal/Rectal Procedure	T		X	
0155	Level II Anal/Rectal Procedure	T		X	
0156	Level II Urinary and Anal Procedures	T		X	
0160	Level I Cystourethroscopy and other Genitourinary Procedures	T		X	
0161	Level II Cystourethroscopy and other Genitourinary Procedures	T		X	
0162	Level III Cystourethroscopy and other Genitourinary Procedures	T		X	
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	T		X	
0164	Level I Urinary and Anal Procedures	T		X	
0165	Level III Urinary and Anal Procedures	T		X	
0188	Level II Female Reproductive Proc	T	X	X	
0189	Level III Female Reproductive Proc	T	X	X	
0191	Level I Female Reproductive Proc	T	X	X	
0192	Level IV Female Reproductive Proc	T	X	X	
0193	Level V Female Reproductive Proc	T	X	X	
0194	Level VI Female Reproductive Proc	T	X	X	
0195	Level VII Female Reproductive Proc	T	X	X	

TABLE 3.—APC GROUPS PROPOSED TO BE CHANGED IN 2002—Continued

APC	Title	SI	APC panel	2 times	Other
0196	Dilation and Curettage	T		X	
0203	Level V Nerve Injections	T	X		
0204	Level VI Nerve Injections	T	X		
0206	Level III Nerve Injections	T	X		
0207	Level IV Nerve Injections	T	X		
0208	Laminotomies and Laminectomies	T	X		
0209	Level II Extended EEG Studies and Sleep Studies	S		X	
0212	Level II Nervous System Injections	T	X		
0213	Level I Extended EEG Studies and Sleep Studies	S		X	
0215	Level I Nerve and Muscle Tests	S	X	X	
0216	Level III Nerve and Muscle Tests	S	X	X	
0217	Level III Nerve and Muscle Tests	S		X	
0218	Level II Nerve and Muscle Tests	S		X	
0230	Level I Eye Tests & Treatments	S		X	X
0231	Level III Eye Tests & Treatments	S		X	
0232	Level I Anterior Segment Eye	S		X	
0233	Level II Anterior Segment Eye	T		X	
0234	Level III Anterior Segment Eye Procedures	T		X	
0235	Level I Posterior Segment Eye Procedures	T		X	
0236	Level II Posterior Segment Eye Procedures	T		X	
0237	Level III Posterior Segment Eye Procedures	T		X	
0238	Level I Repair and Plastic Eye Procedures	T		X	
0239	Level II Repair and Plastic Eye Procedures	T		X	
0245	Level I Cataract Procedures without IOL Insert	T		X	
0249	Level II Cataract Procedures without IOL Insert	T		X	
0251	Level I ENT Procedures	T		X	
0252	Level II ENT Procedures	T		X	
0253	Level III ENT Procedures	T		X	
0254	Level IV ENT Procedures	T		X	
0256	Level V ENT Procedures	T		X	
0259	Level VI ENT Procedures	T		X	
0260	Level I Plain Film Except Teeth	X		X	
0261	Level II Plain Film Except Teeth Including Bone Density Measurement	X		X	
0263	Level I Miscellaneous Radiology Procedures	X		X	
0264	Level II Miscellaneous Radiology Procedures	X		X	
0265	Level I Diagnostic Ultrasound Except Vascular	X		X	
0266	Level II Diagnostic Ultrasound Except Vascular	S		X	
0269	Level I Echocardiogram Except Transesophageal	S		X	
0271	Mammography	S			X
0272	Level I Fluoroscopy	X		X	
0279	Level I Angiography and Venography except Extremity	S	X		
0280	Level II Angiography and Venography	S	X		
0282	Miscellaneous Computerized Axial Tomography	S		X	X
0283	Computerized Axial Tomography with Contrast	S			X
0284	Magnetic Resonance Imaging and Angiography with Contrast	S			X
0287	Complex Venography	S	X		
0288	CT, Bone Density	S		X	
0289	Needle Localization for Breast Biopsy	X	X		
0291	Level I Diagnostic Nuclear Medicine Excluding Myocardial Scans	S		X	
0292	Level II Diagnostic Nuclear Medicine Excluding Myocardial Scans	S		X	
0300	Level I Radiation Therapy	S		X	
0301	Level II Radiation Therapy	S		X	
0302	Level III Radiation Therapy	S		X	
0304	Level I Therapeutic Radiation Treatment Preparation	X	X		
0305	Level II Therapeutic Radiation Treatment Preparation	X	X		
0312	Radioelement Applications	S	X		
0332	Computerized Axial Tomography w/o Contrast	S		X	X
0333	CT Angio and Computerized Axial Tomography w/o Contrast followed by with Contrast.	S		X	X
0335	Magnetic Resonance Imaging, Temporomandular Joint	S			X
0336	Magnetic Resonance Angiography and Imaging without Contrast	S		X	X
0337	Magnetic Resonance Imaging and Angiography w/o Contrast followed by with Contrast.	S			X
0338	Magnetic Resonance Angiography, Chest and Abdomen with or w/o Contrast	S			X
0339	Observation	X	X		
0340	Minor Ancillary Procedures	X		X	
0345	Level I Transfusion Laboratory Procedures	X		X	
0346	Level II Transfusion Laboratory Procedures	X		X	
0347	Level III Transfusion Laboratory Procedures	X		X	
0352	Level II Injections	X		X	
0353	Level II Allergy Injections	X	X		
0355	Level I Immunizations	K		X	

TABLE 3.—APC GROUPS PROPOSED TO BE CHANGED IN 2002—Continued

APC	Title	SI	APC panel	2 times	Other
0356	Level II Immunizations	K		X	
0359	Level I Injections	K		X	
0360	Level I Alimentary Tests	X		X	
0361	Level II Alimentary Tests	X		X	
0364	Level I Audiometry	X		X	
0365	Level II Audiometry	X		X	
0367	Level I Pulmonary Test	X		X	
0368	Level II Pulmonary Tests	X		X	
0369	Level III Pulmonary Tests	X		X	
0371	Level I Allergy Injections	X	X		
0689	Electronic Analysis of Cardioverter-Defibrillators	S	X		
0690	Electronic Analysis of Pacemakers and other Cardiac Devices	S	X		
0691	Electronic Analysis of Programmable Shunts/Pumps	S	X		
0692	Electronic Analysis of Neurostimulator Pulse Generators	S	X		
0693	Level II Breast Reconstruction	T		X	
0694	Level III Excision/Biopsy	T		X	
0695	Level VII Debridement & Destruction	T		X	
0696	Repair/Replacement of Cardioverter-Defibrillators	T	X		
0697	Level II Echocardiogram Except Transesophageal	S		X	
0698	Level II Eye Tests & Treatments	S		X	
0699	Level IV Eye Tests & Treatment	T		X	
0982	New Technology—Level XII ($2500–3000)	T			X
0983	New Technology—Level XIV ($3000–3500)	T			X
0984	New Technology—Level XV ($3500–5000)	T			X
0985	New Technology—Level XVI ($5000–6000)	T			X

D. Recalibration of APC Weights for CY 2002

Section 1833(t)(9)(A) of the Act requires that the Secretary review and revise the relative payment weights for APCs at least annually beginning in 2001 for application in 2002. In the April 7, 2000 final rule (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group. Except for some reweighting due to APC changes, these relative weights continued to be in effect for 2001. (See the November 13, 2000 interim final rule (65 FR 67824–67827).)

To recalibrate the relative APC weights for services furnished on or after January 1, 2002 and before January 1, 2003, we are proposing to use the same basic methodology that we described in the April 7, 2000 final rule to recalibrate the relative weights for 2002. That is, we would recalibrate the weights based on claims and cost report data for outpatient services. We propose to use the most recent available data to construct the database for calculating APC group weights. For the purpose of recalibrating APC relative weights for 2002, the most recent available claims data are the approximately 98 million final action claims for hospital outpatient department services furnished on or after July 1, 1999 and before July 1, 2000. We matched these claims to the most recent cost report filed by the individual hospitals represented in our claims data. The APC relative weights would continue to be based on the median hospital costs for services in the APC groups.

The methodology we followed to calculate the APC relative weights proposed for CY 2002 is as follows:

- We excluded from the data approximately 15.4 million claims for those bill and claim types that would not be paid under the OPPS (for example, bill type 72X for dialysis services for patients with ESRD).
- Using the most recent available cost report from each hospital, we converted billed charges to costs and aggregated them to the procedure or visit level first by identifying the cost-to-charge ratio specific to each hospital's cost centers (''cost center specific cost-to-charge ratios'' or CCRs) and then by matching the CCRs to revenue centers used on the hospital's 1999–2000 outpatient bills. The CCRs included operating and capital costs but excluded costs paid on a reasonable cost basis that are described elsewhere of this preamble.
- We eliminated from the hospital CCR data 283 hospitals that we identified as having reported charges on their cost reports that were not actual charges (for example, they make uniform charges for all services).
- We calculated the geometric mean of the total operating CCRs of hospitals remaining in the CCR data. We removed from the CCR data 67 hospitals whose total operating CCR exceeded the geometric mean by more than 3 standard deviations.
- We excluded from our data approximately 1.8 million claims from the hospitals that we removed or trimmed from the hospital CCR data.
- We matched revenue centers from the remaining universe of approximately 80.8 million claims to CCRs of 5,653 hospitals.
- We separated the 80.8 million claims that we had matched with a cost report into two distinct groups: single-procedure claims and multiple-procedure claims. Single-procedure claims were those that included only one HCPCS code (other than laboratory and incidentals such as packaged drugs and venipuncture) that could be grouped to an APC. Multiple-procedure claims included more than one HCPCS code that could be mapped to an APC. There were approximately 36.4 million single-procedure claims and 44.4 million multiple-procedure claims.
- To calculate median costs for services within an APC, we used only single-procedure bills. We did not use multiple-procedure claims because we are not able to specifically allocate charges or costs for packaged items and services such as anesthesia, recovery room, drugs, or supplies to a particular procedure when more than one significant procedure or medical visit is billed on a claim. Use of the single-procedure bills minimizes the risk of improperly assigning costs to the wrong procedure or visit.
- For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each

revenue center charge by the appropriate hospital-specific CCR. If the appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or to the hospital's overall cost-to-charge ratio for outpatient department services. We excluded from this calculation all charges associated with HCPCS codes previously defined as not paid under the OPPS (for example, laboratory, ambulance, and therapy services).

• To calculate the per-service costs, we used the charges shown in the revenue centers that contained items integral to performing the service. These included those items that we previously discussed as being subject to our proposed packaging provision. For instance, in calculating the surgical procedure cost, we included charges for the operating room, treatment rooms, recovery, observation, medical and surgical supplies, pharmacy, anesthesia, casts and splints, and donor tissue, bone, and organ. For medical visit cost estimates, we included charges for items such as medical and surgical supplies, drugs, and observation in those instances where it is still packaged. See sections II.C.1 and II.C.2 of this preamble for a discussion and complete listing of the revenue centers that we are proposing to use to calculate per-service costs.

• We standardized costs for geographic wage variation by dividing the labor-related portion of the operating and capital costs for each billed item by the current FY 2001 hospital inpatient prospective payment system wage index published in the **Federal Register** on August 1, 2000 (65 FR 47054). We used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. A more detailed discussion of wage index adjustments is found in section III of this preamble.

• We summed the standardized labor-related cost and the nonlabor-related cost component for each billed item to derive the total standardized cost for each procedure or medical visit.

• We removed extremely unusual costs that appeared to be errors in the data using a trimming methodology analogous to what we use in calculating the DRG weights for the hospital inpatient PPS. That is, we eliminated any bills with costs outside of 3 standard deviations from the geometric mean.

• After trimming the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC, including, to the extent possible, the proposed APC changes described elsewhere in this preamble.

• We calculated the median cost, weighted by procedure volume, for each APC.

• Using the weighted median APC costs, we calculated the relative payment weights for each APC. We scaled all the relative payment weights to APC 0601, Mid-level clinic visit, because it is one of the most frequently performed services in the hospital outpatient setting. This approach is consistent with that used in developing relative value units for the Medicare physician fee schedule. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601, to derive the relative payment weight for each APC. The median cost for APC 0601 is $54.00.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes and wage index changes be made in a manner that assures that aggregate payments under the OPPS for 2002 are neither greater than nor less than the aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2001 relative weights to aggregate payments using the CY 2002 proposed weights. Based on this comparison, we are proposing to make an adjustment of 1.022 to the weights. The weights that we are proposing for 2002, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B.

III. Wage Index Changes

Under section 1833(t)(2)(D) of the Act, we are required to determine a wage adjustment factor to adjust for geographic wage differences, in a budget neutral manner, that portion of the OPPS payment rate and copayment amount that is attributable to labor and labor-related costs.

We used the proposed Federal fiscal year (FY) 2002 hospital inpatient PPS wage index to make wage adjustments in determining the proposed payment rates set forth in this proposed rule. The proposed FY 2002 hospital inpatient wage index published in the May 4, 2001 **Federal Register** (66 FR 22821) is reprinted in this proposed rule as Addendum H, Wage Index for Urban Areas; Addendum I, Wage Index for Rural Areas; and Addendum J, Wage Index for Hospitals That Are Reclassified. We propose to use the final FY 2002 hospital inpatient wage index to calculate the payment rates and coinsurance amounts that we will publish in the final rule implementing the OPPS for calendar year (CY) 2002.

IV. Copayment Changes

We note that in section 1833(t) of the Act, the terms ''copayment'' and ''coinsurance'' appear to be used interchangeably. To be consistent with CMS usage, we make a distinction between the two terms throughout this preamble. We propose to make conforming changes to part 419 of the regulations to reflect the following usage:

• ''Coinsurance'' means the percent of the Medicare-approved amount that beneficiaries pay for a service furnished in the hospital outpatient department (after they meet the Part B deductible).

• ''Copayment'' means the set dollar amount that beneficiaries pay under the OPPS. For example, if the payment rate for an APC is $200 and the beneficiary is responsible for paying $50, the copayment is $50 and the coinsurance is 25 percent.

A. BIPA 2000 Coinsurance Limit

As discussed in section I.C of this preamble, certain provisions of BIPA 2000 affect beneficiary copayment amounts under the OPPS. Section 111 of the BIPA added section 1833(t)(8)(C)(ii) of the Act, to accelerate the reduction of beneficiary copayment amounts, providing that, for services furnished on or after April 1, 2001 and before January 1, 2002, the national unadjusted coinsurance for an APC cannot exceed 57 percent of the APC payment rate. The statute provides for further reductions in future years so that the national unadjusted coinsurance for an APC cannot exceed 55 percent in 2002 and 2003, 50 percent in 2004, 45 percent in 2005, and 40 percent in 2006 and thereafter.

We implemented the reduction in beneficiary copayments for 2001 effective April 1, 2001 through changes to the OPPS PRICER software used to calculate OPPS payments to hospitals from the Medicare Program and beneficiary copayments.

We would revise § 419.41 to conform the regulations text to this provision.

B. Impact of BIPA 2000 Payment Rate Increase on Coinsurance

Under the statute as enacted by BBA 1997, APC payment rates for 2001 were to be based on the payment rates for 2000 increased by the inpatient hospital market basket percentage increase minus 1 percentage point; however, section 401 of the BIPA 2000 increased APC payment rates for 2001 to reflect an update based on the full market basket

percentage increase. The Congress intended for the increased payment to be in effect for the entire calendar year 2001; however, to provide us sufficient time to make the change, the Congress adopted a special payment rule for 2001. Under section 401(c) of the BIPA, the payment rates in effect for services furnished on or after January 1, 2001 and before April 1, 2001 are the rates as determined under the statute prior to the enactment of BIPA. For services furnished on or after April 1, 2001 and before January 1, 2002 the payment rates reflect the full market basket update and are further increased by 0.32 percent to account for the timing delay in implementing the full market basket update for 2001. The 0.32 percent increase is a temporary increase that applies only to the period April 1 through December 31, 2001 and is not considered in updating the OPPS conversion factor for 2002. The increase in APC payment rates for 2001 was implemented effective April 1, 2001 through changes to the OPPS PRICER software. We would revise § 419.32 to conform to the statute.

The section 401 increase to the APC payment rates affected beneficiary copayments in several ways. In cases for which the beneficiary coinsurance was already based on 20 percent of the APC payment rate, the increase in the APC payment rate caused a corresponding increase in the copayment for the APC. For all other APCs, the copayment amount remained at the same level. In addition, because the minimum copayment amount for an APC, which is the lowest amount a provider may elect to charge, if it chooses to reduce copayments for an APC, is based on 20 percent of the APC amount, the increase to an APC payment rate under section 401 of BIPA, resulted in an increase to the minimum copayment amount for each APC.

C. Coinsurance and Copayment Changes Resulting From Change in an APC Group

National unadjusted copayment amounts for the original APCs that went into effect on August 1, 2000 were, by statute, based on 20 percent of the national median charge billed for services in the APC group during calendar year 1996, trended forward to 1999, but could be no lower than 20 percent of the APC payment rate. Although the BBA 1997 specified how copayments were to be determined initially, the statute does not specify how copayments are to be determined in the future as the APC groups are recalibrated or as individual services are reclassified from one APC group to another. In this section, we are proposing the method we intend to apply in determining copayments for new APCs (that is, those created after 2001) and for APCs that are revised because of recalibration and reclassification.

In developing a proposed approach to be used in determining copayments for new or revised APCs, we took into account the following:

- One of the Congress's goals in authorizing an OPPS is to reduce beneficiary copayment liability until the copayment for every hospital outpatient service equals 20 percent of the prospectively determined payment rate for that service. Therefore, when given two possible copayment amounts or coinsurance percentages for a service as the result of an APC change, we should opt for the lower value.
- In general, we should use the coinsurance percentage (that is, the percentage of the total payment rate represented by the copayment amount) as the factor for comparison of the old versus the new copayment amount rather than a copayment dollar amount.
- Notwithstanding any changes, the coinsurance for an APC cannot be lower than 20 percent of the payment rate for an APC group.
- Notwithstanding any changes, the coinsurance for an APC cannot exceed 55 percent of the payment rate for an APC in 2002 or the applicable copayment limits under section 1833(t)(8)(C)(ii) of the Act in subsequent years.

The following describes how we propose to determine copayment amounts for new and revised APCs for 2002 and subsequent years:

1. If a newly created APC group consists of services that were not included in the 1996 data base or whose charges were not separately calculated in that data base (that is, the services were excluded or packaged) the unadjusted copayment amount would be 20 percent of the APC payment rate.

2. If recalibrating the relative payment weights results in an APC having a decrease in its payment rate for a subsequent year, the unadjusted copayment amount will be calculated so that the coinsurance percentage for the APC remains the same that it was before the payment rate decrease. For example, assume the APC had a payment rate of $100 and an unadjusted copayment amount of $50, resulting in a coinsurance percentage of 50 percent. If the new payment rate for the APC is lowered to $80, the copayment amount is calculated using the prior coinsurance percentage of 50 percent; therefore, the new copayment amount would be 50 percent of $80 or $40.

3. If recalibrating the relative payment weights results in an APC having an increase in its payment rate for a subsequent year, the unadjusted copayment amount would be calculated so that the copayment dollar amount for the APC remains the same as it was before the payment rate increase. That is, the unadjusted copayment amount would not change. For example, assume the APC had a payment rate of $100 and an unadjusted copayment amount of $60 (a coinsurance percentage of 60 percent). If the new payment rate for the APC is increased to $150, the unadjusted copayment amount would remain at $60 (a coinsurance percentage of 40 percent).

4. If a newly created APC group consists of services from two or more existing APCs, the unadjusted copayment amount would be calculated based on the lowest coinsurance percentage of the contributing APCs. For example, a new APC is created by moving some or all of the services from two existing APCs into the new APC. Assume that one contributing APC had a payment rate of $100 and an unadjusted copayment amount of $40, coinsurance percentage of 40 percent. Assume the other contributing APC had a payment rate of $150 and an unadjusted copayment amount of $75, a coinsurance percentage of 50 percent. If the new APC had a payment rate of $130, the unadjusted copayment amount for the new APC would be based on a coinsurance percentage of 40. The unadjusted copayment amount for the new APC would be 40 percent of $130, or $52.

5. If an APC payment rate is increased due to a conversion factor update, the unadjusted copayment amount for the APC would not change.

V. Outlier Policy Changes

For OPPS services furnished before January 1, 2002, section 1833(t)(5)(D) of the Act explicitly authorizes the Secretary to apply the outlier payment provision based upon all of the OPPS services on a bill. We exercised that authority and, since the beginning of the OPPS on August 1, 2000, we have calculated outlier payments in the aggregate for all OPPS services that appear on a bill. Under this proposed rule, beginning January 1, 2002, we will calculate outlier payments based on each individual OPPS service. We propose to revise the aggregate method that we are currently using to calculate outlier payments and begin to determine outliers on a service-by-service basis for

OPPS services furnished on or after January 1, 2002.

One difficulty we face with calculating outliers based on individual services is how to treat the charges for packaged services (for example, drugs, supplies, anesthesia, and equipment) when more than one OPPS service appears on a bill. These packaged services do not in themselves generate an APC payment but their charges must be taken into account to determine the cost of a service such as a surgical or diagnostic procedure or medical visit that does generate an APC payment. When more than one HCPCS code that will result in an APC payment appears on a bill, it is currently impossible to determine which packaged service is associated with an individual OPPS payable service. For example, when multiple surgical procedures are performed on the same day, we cannot determine how much of the operating room, drug, supply, anesthesia, or recovery room charge is attributable to each procedure. Similarly, if a medical visit and a surgical procedure occur on the same day, we cannot accurately determine how much of the charge for any drug, supply, or other packaged service that appears on the bill is attributable to each individual OPPS service.

One solution would be to require hospitals to submit separate bills for each OPPS service so that we can be certain that the correct packaged services attributable to the individual OPPS service will be taken into account in determining an outlier payment for that service. We believe, however, such a requirement would be excessively burdensome to hospitals and would greatly increase fiscal intermediary workloads. In addition, billing of individual services for the same day on separate bills would prohibit us from applying the correct coding edits. Finally, we believe that the limit on outlier payments (up to 2.5 percent of the total OPPS payments in each year before 2004 and up to 3 percent for subsequent years) does not justify the burden that would result from requiring separate bills for each OPPS service.

Another approach we considered is to allocate the charges for any packaged service among the individual OPPS services that appear on the bill. We considered two possible ways to do this. First, we could divide the packaged charges equally among the OPPS services so that if there were three services that generated APC payments, one third of the charges for the packaged services would be assigned to each OPPS service. We also considered dividing the total packaged charges among the OPPS services based on the ratio of the APC payment rate for an individual OPPS service to the total APC payment rates for all services on the bill. Thus, if a service resulted in an APC rate of $200 and the total APC payment rates for all services on the bill were $2,000, that individual APC would be allocated 10 percent of the packaged charges appearing on the bill.

We prefer using one of the approaches that would allocate packaged charges among the APCs on a bill to avoid disruptive billing changes. Of the two ways to allocate charges for packaged services, we are proposing that charges be allocated to each OPPS service based on the percent the APC payment rate for that service bears to the total APC rates for all OPPS services on the bill. We believe that this allocation method is somewhat more precise than simply dividing evenly the total packaged charges by the number of APCs on the bill.

We also propose to convert charges to costs for calculating outlier payments by continuing to apply a single overall hospital-specific cost-to-charge ratio instead of applying hospital-specific departmental cost-to-charge ratios. There is no universal crosswalk of revenue codes to cost report cost centers that is used by all hospitals. Although departmental cost-to-charge ratios are more precise for purposes of determining costs of specific services, hospitals have considerable discretion in assigning charges billed under specific revenue codes to specific departments on their cost reports. Therefore, we do not have a way of defining, in a uniform manner that is accurate for all hospitals, which department cost-to-charge ratio to apply to a revenue code billed by a hospital. We considered establishing a basic crosswalk that we would apply uniformly to every hospital, but this could result in a distorted or inaccurate model of how some hospitals actually assign charges. Given the appropriate resources, we could gather data from hospitals upon which to base a crosswalk specific to every hospital paid under the OPPS. But collecting these data would impose significant burden and administrative costs on hospitals and on our contractors. Given that outliers represent only 2 to 3 percent of total OPPS expenditures, we believe that the increased accuracy in calculating outlier payments that we could gain would not be sufficient to justify the significant additional administrative burden and cost that would be required. For this reason, we are proposing to continue to apply a single hospital-specific outpatient cost-to-charge ratio to convert billed charges to costs for calculating outlier payments.

As explained in the April 7, 2000 final rule (65 FR 18498), we set a target for outlier payments at 2.0 percent of total payments. We also explained, for purposes of simulating payments to calculate outlier thresholds, that we set the parameters for determining outlier payments as if the target were 2.5 percent. We believed that it would be likely that using simulation 1996 claims data would overstate the percentage of payments that would be made. Based on the simulations, we set a threshold for outlier payments at 2.5 times the claim cost and a payment percent of 75 percent of the cost above the threshold for both 2000 and 2001.

In setting the 2002 outlier threshold and payment percentage, we account for the charge to service level rather than claim level outlier calculation. In this proposed rule, we would again set the target for outlier payment at 2.0 percent. However, because we believe that the claims data we are using to set the 2002 proposed payment rates reflect much better coding of services than did the 1996 data, we would set these parameters to reach a target of 2.0 percent (rather than 2.5 percent). Based on our simulations, the proposed threshold for 2002 is 3 times the service costs and the proposed payment percentage for costs above that threshold is set at 50 percent.

VI. Other Policy Decisions and Proposed Changes

A. Change in Services Covered Within the Scope of the OPPS

Section 1833(t)(1)(B) of the Act defines the term ''covered OPD services'' that are to be paid under the OPPS. ''Covered OPD services'' are ''hospital outpatient services designated by the Secretary'' and include ''inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (i) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (ii) is not so entitled'' (that is, ''Part B-only'' services). ''Part B-only'' services are certain ancillary services furnished to inpatients for which the hospital receives payment under Medicare Part B. Section 3110 of the Medicare Intermediary Manual and section 2255C of the Medicare Carriers Manual specify these services as diagnostic tests; X-ray and radioactive isotope therapy; surgical dressings, splints and casts; prosthetic devices; and limb braces and trusses and artificial limbs and eyes.

In the April 7, 2000 final rule, we included inpatient ''Part B-only'' services within the definition of services payable under the OPPS (68 FR 18543). We have subsequently been approached by representatives of some hospitals that do not have outpatient departments and that, therefore, do no billing for Part B services except for a relatively few ''Part B-only'' services that they furnish to their inpatients. That is, the only bills these hospitals would ever submit for Part B payment are for the ancillary services designated as ''Part B-only'' services. These hospitals are concerned about the administrative burden and prohibitive costs they would incur if they were to change their billing systems to accommodate OPPS requirements solely to receive payment for ''Part B-only'' services.

We recognize that there are certain hospitals that do not have outpatient departments and that do not provide outpatient department services but that do provide inpatient services to Medicare beneficiaries. The only services these hospitals bill under OPPS are services furnished to inpatients. That is, these are special billings under the Part B-only benefit for limited ancillary services provided to beneficiaries who are admitted to the hospital as inpatients and who are not receiving services on an outpatient basis. We further acknowledge that the expense of converting their billing systems to accommodate the OPPS is disproportionate to the Part B revenues that these hospitals receive. Therefore, we are proposing to revise § 419.22 by adding subparagraph (r) to exclude from payment under the OPPS Part B-only services that are furnished to inpatients of hospitals that do no other billing for hospital outpatient services under Part B.

Under this proposed revision of the regulations, hospitals with outpatient departments would continue to bill under the OPPS for Part B-only services that they furnish to their inpatients. However, a hospital that does not have an outpatient department would be unable to bill under the OPPS for any Part B-only service the hospital furnished to its inpatients because those services would not fall within the scope of covered OPD services. If a hospital with no outpatient department is currently billing under the OPPS, the hospital would have to revert to its previous payment methodology for services furnished on or after January 1, 2002. That methodology would be an all-inclusive rate for hospitals paid that way prior to the implementation of OPPS and reasonable cost for other hospitals.

We do not know at this time, and are not sure it would be possible to ascertain, the potential number of hospitals that would be affected by this regulatory change. However, we expect the financial impact on the program to be small, because this revised rule would apply only to the relatively few hospitals that are billing for the very limited range of Part B-only services for a small number of beneficiaries.

B. Categories of Hospitals Subject to and Excluded From the OPPS

In § 419.20(b) of the regulations, certain hospitals in Maryland that qualify under section 1814(b)(3) of the Act for payment under the State's payment system are excluded from the OPPS. Critical access hospitals (CAHs) that are paid under a reasonable cost-based system as required under section 1834(g) of the Act are also excluded. In addition, we stated in the April 7, 2000 final rule that the outpatient services provided by the hospitals of the Indian Health Services (IHS) will continue to be paid under separately established rates. We also noted that we intended to consult with the IHS and develop a plan to transition these hospitals into OPPS. With these exceptions, the OPPS applies to all other hospitals that participate in the Medicare program.

It has been brought to our attention that under the statute, hospitals located in Guam, Saipan, American Samoa, and the Virgin Islands are excluded from the hospital inpatient PPS. These hospitals currently lack a charge structure for billing and, in some cases, are not equipped to prepare a cost report. They furnish very few services that would be subject to the OPPS. In addition, we believe that because of their distant locations, they incur costs that might not be adequately recognized by a PPS. Prior to implementation of the OPPS, each of the hospitals in Guam, American Samoa, Saipan, and the Virgin Islands had its own unique Medicare payment methodology for the outpatient services they furnish. In light of these factors, we are proposing to revise § 419.20 of the regulations by adding paragraph (b)(3) to exclude these hospitals from OPPS consistent with their treatment under inpatient PPS. In addition, we would revise that section to include the hospitals of the IHS so that it is clear that they are excluded until we develop a plan to include them. We would note that it may also be possible to include the hospitals in the territories in the OPPS in the future.

C. Conforming Changes: Additional Payments on a Reasonable Cost Basis

Hospitals subject to the OPPS are paid for certain items and services that are outside the scope of the OPPS on a reasonable cost or other basis. Payments for the following services are made on a reasonable cost basis or otherwise applicable methodology:

a. The direct costs of medical education as described in § 413.86.

b. The costs of nursing and allied health programs as described in § 413.85.

c. The costs associated with interns and residents not in approved teaching programs as described in § 415.202.

d. The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based payment for teaching physicians under § 415.160.

e. The costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c).

f. Bad debts for uncollectible deductible and coinsurance amounts as described in § 413.80(b).

g. Organ acquisition costs paid under Part B. Interim payments for these services are made on a biweekly basis and final payments are determined at cost report settlement.

We would revise § 419.2(c) to make conforming changes that reflect the exclusion of these costs from the OPPS rates.

D. Hospital Coding for Evaluation and Management (E/M) Services

In the April 7, 2000 final rule, we emphasized the importance of each facility accurately assessing the intensity, resource use, and charges for evaluation and management (E/M) services, in order to ensure proper reporting of the service provided. We stated that ''the billing information that the hospitals report during the first years of implementation of the hospital outpatient PPS will be vitally important to our revision of weights and other adjustments that affect payment in future years.'' (65 FR 18451)

We went on to state, ''We realize that while these HCPCS codes appropriately represent different levels of physician effort, they do not adequately describe nonphysician resources. However, * * * the same concept can be applied to each code in terms of the differences in resource utilization. Therefore, each facility should develop a system for

mapping the provided services or combination of services furnished to the different levels of effort represented by the codes * * *. We will hold each facility accountable for following its own system for assigning the different levels of HCPCS codes. As long as the services furnished are documented and medically necessary and the facility is following its own system, which reasonably relates the intensity of hospital resources to the different levels of HCPCS codes, we will assume that it is in compliance with these reporting requirements as they relate to the clinic/emergency department visit code reported on the bill. Therefore, we would not expect to see a high degree of correlation between the code reported by the physician and that reported by the facility * * *. We will work with the American Hospital Association and the American Medical Association to propose the establishment of appropriate facility-based patient visit codes * * *.''

We understand that facilities have developed several different systems for determining resource consumption to assign proper E/M codes. Some of these systems are based on clinical (''condition'') criteria, and others are based on weighted scoring criteria. We continue to believe that proper facility coding of E/M services is critical for assuring appropriate payments. In order to achieve this, we are interested in developing and implementing a standardized coding process for facility reporting of E/M services. This process could include the use of current HCPCS codes or the establishment of new HCPCS codes in conjunction with guidelines for facility coding.

At this time, we are soliciting comments from hospitals and other interested parties on this issue. We will submit these comments to the APC Advisory Panel and ask for the Panel's recommendations regarding the development and implementation of a facility coding process for E/M services. In order to ensure consideration by the Panel, comments must be received by November 1, 2001. Send comments regarding facility coding of E/M services to: OPPS–E/M coding, Centers for Medicare & Medicaid Services, Mailstop C4–05–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. CMS will review both the public comments and the recommendations from the Panel and propose a coding process in the proposed rule for 2003.

E. Annual Drug Pricing Update

Under the OPPS, we pay for drugs and biologicals in one of three ways.

1. Packaged Payment

As we explain in the April 7, 2000 final rule, we generally package the cost of drugs, biologicals, and pharmaceuticals into the APC payment rate for the primary procedure or treatment with which the drugs are usually furnished (65 FR 18450). No separate payment is made under the OPPS for drugs, biologicals, and pharmaceuticals whose costs are packaged into the APCs with which they are associated.

2. Transitional Pass-Through Payments for Eligible Drugs and Biologicals

As we explain in the April 7, 2000 final rule and in section VII of this preamble, the BBRA 1999 provided for special transitional pass-through payments for a period of 2 to 3 years for the following drugs and biologicals:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act;
- Current drugs and biologic agents used for treatment of cancer;
- Current radiopharmaceutical drugs and biological products; and
- New drugs and biologic agents in instances where the item was not being paid for as a hospital outpatient service as of December 31, 1996, and where the cost of the item is ''not insignificant'' in relation to the hospital outpatient PPS payment amount.

In this context, ''current'' refers to those items for which hospital outpatient payment was being made on August 1, 2000, the date on which the OPPS was implemented. A ''new'' drug or biological is a product that was not paid as a hospital outpatient service prior to January 1, 1997 and for which the cost is not insignificant in relation to the payment for the APC to which it is assigned.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs as the amount determined under section 1842(o) of the Act, that is, 95 percent of the applicable average wholesale price (AWP). Section 1833(t)(6)(D)(i) of the Act also sets the amount of additional payment for pass-through-eligible drugs and biologicals (the pass-through payment amount). The pass-through payment amount is the difference between 95 percent of the applicable AWP and the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. Therefore, as we explain in the April 7 final rule (65 FR 18481), in order to determine the correct pass-through payment amount, we first had to determine the cost that was packaged for the drug or biological within its related APC. In order to determine this amount, we used the following methodology, which we also explain in the April 7 final rule.

When we implemented the OPPS on August 1, 2000, costs for drugs and biologicals eligible for transitional pass-through payment were, to the extent possible, not included in the payment rates for the APC groups into which they had been packaged prior to enactment of the BBRA 1999. That is, to the extent feasible, we removed from the APC groups into which they were packaged, the costs of as many of the pass-through eligible drugs and biologicals as we could identify in the 1996 claims data. Then, we assigned each drug and biological eligible for a pass-through payment to its own, separate APC group, the total payment rate for which was set at 95 percent of the applicable AWP.

Next, in order to establish the applicable beneficiary copayment amount and pass-through payment amount, we had to determine the cost of the pass-through eligible drug or biological that would have been included in the payment rate for its associated APC had the drug or biological been packaged. We used hospital acquisition costs as a proxy for the amount that would have been packaged, based on data taken from an external survey of hospital drug costs. (See the April 7, 2000 final rule (65 FR 18481)).

We imputed the acquisition cost for the various drugs and biologicals in pass-through APCs by multiplying their applicable AWP by one of the following ratios. The following ratios are based on the survey data, and they represent, on average, hospital drug acquisition cost relative to AWP:

- For drugs with one manufacturer (sole-source), the ratio of acquisition cost to AWP equals 0.68.
- For drugs with more than one manufacturer (multi-source), the ratio of acquisition cost to AWP equals 0.61.
- For drugs with more than one manufacturer and with generic competitors, the ratio of acquisition cost to AWP equals 0.43.

In accordance with section 1833(t)(7) of the Act, we base beneficiary copayment amounts for pass-through drugs only on that portion of the drug's cost that would have been included in the payment amount for an associated APC had the drug been packaged. Therefore, having determined the hospital acquisition cost of the drug based on the ratios described above, we multiply the acquisition cost by 20

percent to calculate the beneficiary copayment for the pass-through drug or biological APCs. Finally, to calculate the actual pass-through payment amount, we subtract from the applicable 95 percent of AWP the hospital acquisition cost less the beneficiary copayment amount.

To illustrate this payment methodology, consider a current sole source drug with an average wholesale price (AWP) of $100 per dose. Under section 1842(o) of the Act, the total allowed payment for the drug is $95, that is, 95 percent of AWP. We impute the cost of the drug based on survey data, which indicate hospital acquisition costs for this type of drug on average to be 68 percent of its AWP (or $68). In the absence of the pass-through provisions, this cost would be packaged into the APC payment for the procedure or service with which the drug or biological is furnished. Therefore, we define the beneficiary coinsurance as 20 percent of the imputed cost of $68, resulting in a copayment amount $13.60. The pass-through payment amount is $27 (the difference between 95 percent of AWP ($95) and the portion of the APC payment that is based on the cost of the drug ($68)). The total Medicare program payment in this example equals $81.40 (cost of the drug in the APC ($68) less beneficiary copay ($13.60) plus pass-through payment ($27)).

In this proposed rule, we are clarifying that, for purposes of calculating transitional pass-through payment amounts, we make no distinction between new and current drugs and biologicals. Rather, we assume that drugs and biologicals defined as ''new'' under section 1833(t)(6)(A)(iv)(I) of the Act, that is, for which payment was not being made as of December 31, 1996, nonetheless replace or are alternatives to drugs, biologicals, or therapies whose costs would have been reflected in our 1996 claims data and, thus, have been packaged into an associated APC. Therefore, we assume that our imputed acquisition cost, based on the external survey data, represents that portion of the APC payment attributable to new as well as current drugs and biologicals. For that reason, we are discontinuing use of the payment status indicator ''J'' that we introduced in the November 13, 2000 final rule to designate a ''new'' drug/biological pass-through. Instead, we would assign payment status indicator ''G'' to both current and new drugs that are eligible for pass-through payment under the OPPS. (Addendum D lists the definition of the OPPS payment status indicators.)

3. Separate APCs for Drugs Not Eligible for Transitional Pass-Through Payment

There are some drugs and biologicals for which we did not have adequate cost data yet that are not eligible for transitional pass-through payments. Beginning with the April 7, 2000 final rule, we created separate APCs for these drugs and biologicals. For example, we did not package into the emergency room visit APCs the various drugs classified as tissue plasminogen activators (tPAs) and other thrombolytic agents, which are used to treat patients with myocardial infarctions. Rather, we created individual APC groups for these drugs to allow separate payment so as not to discourage their use where appropriate.

We based the payment rate for these APCs on median hospital acquisition costs. To determine the hospital acquisition cost for the drugs, we imputed a cost using the same ratios of drug acquisition cost to AWP that we discuss in section VI.E.2. in connection with calculating acquisition costs for transitional pass-through drug payments. That is, we multiplied the AWP for the drug by the applicable ratio (sole or multi-source drug) based on data collected in an external survey of hospital drug acquisition costs.

We set beneficiary co-payment amounts for these drug APCs at 20 percent of the imputed acquisition cost. We use status indicator ''K'' to denote the APCs for drugs, biologicals, and pharmaceuticals that are paid separately from and in addition to the procedure or treatment with which they are associated yet are not eligible for transitional pass-through payment. Refer to Addendum A to identify these APCs.

4. Annual Drug Pricing Update

a. Drugs Eligible for Pass-Through Payments. We used the AWPs reported in the Drug Topics Red Book to determine the payment rates for the pass-through drugs and biologicals. In the November 13, 2000 interim final rule (65 FR 67809), in response to a comment that we update the AWPs for pass-through drugs on a quarterly basis, we stated that, due to the complexity of the new payment system, we would be able to update the rates only on an annual basis. We also noted that the new rates would be effective for the quarter following the publication of the updated AWP values in the Red Book. It was our understanding that, although there are quarterly updates to the AWPs in the Red Book, the annual update is published in April of each year. It was our intention to update the AWPs for drugs each July 1, the quarter following the annual publication, and we did use the April 2001 version of the Red Book to update the APC rates for drugs eligible for pass-through payments. The pass-through payment rates for drugs and biologicals updated for 2001 went into effect July 1, 2001 (Program Memorandum A–01–73, issued on June 1, 2001).

We found that doing an update for all the pass-through drugs and biologicals at mid-year was disruptive to both our computer systems and pricing software. Because it is now our understanding that even though the April publication is the annual printed version of the Red Book, there are quarterly updates available that we can use to update the AWPs. In fact, we have found that since the implementation of the pass-through payments in OPPS, many manufacturers have availed themselves of the Red Book quarterly update system to make frequent and large increases to their AWPs. Therefore, we do not believe it is necessary to wait until publication of the annual Red Book to do an update to the pass-through rates for drugs and biologicals to reflect the most recent AWPs.

Thus, we are proposing to update the APC rates for drugs that are eligible for pass-through payments in 2002 using the July 2001 or October 2001 version of Red Book (depending upon which is available when we develop the final rule). The updated rates effective January 1, 2002 would remain in effect until we implement the next annual update in 2003, when we would again update the AWPs based on the latest quarterly version of the Red Book. This would place the update of pass-through drug prices on the same calendar year schedule as the other annual OPPS updates.

b. Drugs in Separate APCs Not Eligible for Pass-Through Payments. We used the conversion factor published in the November 13, 2000 final rule (65 FR 67827) to update, effective January 1, 2001, the APC rates for the drugs that are not eligible for pass-through payments that are in separate APCs. We also made payment adjustments to these APC groups effective April 1, 2001, as required by section 401(c) of the BIPA, which sets forth a special payment rule that had the effect of providing a full market basket update in 2001.

For 2002, we propose to recalibrate the weights for the APCs for drugs that are not pass-through items and make the other adjustments applicable to the APC groups that we discuss in sections III, IV, and VIII of this proposed rule.

F. Definition of Single-Use Devices

Our definition of a device eligible for pass-through payment includes a criterion whereby eligible devices are used for one patient only and are single use (65 FR 47674, August 3, 2000). In the November 13, 2000 interim final rule, we stated, in response to a comment, that additional pass-through payments would not be made for devices that are reprocessed or reused because they are not single-use items. We further indicated that hospitals submitting pass-through claims for these devices might be considered to be engaging in fraudulent billing practices (65 FR 67822).

Since publishing our November 13, 2000 rule, much has come to our attention regarding reprocessed single-use devices. Reprocessors and professional associations using reprocessed devices commented that, under certain circumstances, the FDA considers reprocessed devices to be single-use devices. The FDA corroborated that it considers previously used single-use devices that have been appropriately reprocessed to be considered to be a single-use device. The reprocessing industry also indicated that reprocessed single use devices are of much lower cost to hospitals than original equipment manufactured single-use devices.

We have learned that the FDA published guidance for the reprocessing of single-use devices (FDA's ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,'' issued August 14, 2000). This document presents a phased-in regulatory scheme for reprocessed devices. As such, we are proposing to follow FDA's guidance on reprocessed single-use device. We would consider reprocessed single-use devices that are otherwise eligible for pass-through payment as part of a category of devices to be eligible for that payment if they meet FDA's most recent regulatory criteria on single-use devices. Also, reprocessed devices must meet any FDA guidance or other regulatory requirements in the future regarding single use. Reprocessed devices adhering to these guidelines would be considered as having met our criterion of approval or clearance by the FDA. We have met with and will continue to meet and coordinate with the FDA concerning that Federal agency's definition and regulation of single-use devices.

Parties advise us that reprocessed devices reduce the costs to hospitals substantially. Therefore, we would expect that the hospital charges on claims submitted for pass-through payments for reprocessed single-use devices would reflect the lower cost of these devices.

G. Criteria for New Technology APCs

1. Background

In the April 7, 2000 final rule (68 FR 18477), we created a set of new technology APCs to pay for certain new technology services under the OPPS. These APCs are intended to pay for new technology services that were not addressed by the transitional pass-through provisions of the BBRA 1999. We indicated that the new technology APCs would be defined on the basis of costs and not the clinical characteristics of a service.

We initially established groups 0970 through 0984 as the new technology APCs with costs ranging from less than $50 to $6,000. The payment rate for each of these APCs is based on the midpoint of a range of costs. For example, the payment for new technology APC 0974, which includes services that cost from $300 to $500, is set at $400.

The new technology APCs that were implemented on August 1, 2000 were populated with 11 new technology services. We state in the April 7, 2000 rule that we will pay for an item or service under a new technology APC for at least 2 years but no more than 3 years, consistent with the term of transitional pass-through payments. After that period of time, during the annual APC update cycle, we stated that we will move the item or service into the existing APC structure based on its clinical attributes and, based on claims data, its resource costs. For a new technology APC, the beneficiary coinsurance is 20 percent of the APC payment rate.

In the April 7, 2000 rule, we specified an application process and the information that must be supplied for us to consider a request for payment under the new technology APCs (65 FR 18478). We also described the five criteria we would use to determine whether a service is eligible for assignment to a new technology APC group. These criteria, which we are currently using, are as follows:

- The item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the service could not have been adequately represented in 1996 data.
- The item or service does not qualify for an additional payment under the transitional pass-through payments provided for by section 1833(t)(6) of the Act as a current orphan drug, as a current cancer therapy drug or biological or brachytherapy, as a current radiopharmaceutical drug or biological product, or as a new medical device, drug, or biological.
- The item or service has a HCPCS code.
- The item or service falls within the scope of Medicare benefits under section 1832(a) of the Act.
- The item or service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act.

2. Proposed Modifications to the Criteria and Process for Assigning Services to New Technology APCs

Based on the experience we have gained and data we have collected since publication of the April 7, 2000 final rule, we are proposing to revise—(a) the definition of what is appropriately paid for under the new technology APCs; (b) the criteria for determining whether a service may be paid under the new technology APCs; (c) the information that we will require to determine eligibility for assignment to a new technology APC; and (d) the length of time we will pay for a service in a new technology APC.

a. Services Paid Under New Technology APCs. We propose to limit eligibility for placement in new technology APCs to complete services or procedures. That is, the following are not eligible for placement in a new technology APC: items, materials, supplies, apparatuses, instruments, implements, or equipment that are used to accomplish a more comprehensive service or procedure.

We would continue to exclude devices or any drug, biologic, radiopharmaceutical, product, or commodity for which payment could be made under the transitional pass-through provisions. We believe that the new technology APCs should be reserved for only those comprehensive services or procedures that are truly new. Individual components of a service or procedure that do not meet the transitional pass-through payment criteria should be incorporated into a current APC and as hospitals begin to use the new items, supplies, or equipment the costs will become incorporated into the weight of the APC. To the extent possible, we believe that hospitals should be making the decision on what items, supplies, and equipment on the basis of efficiency and appropriate treatment of the patient. However, we believe it is appropriate to incorporate truly new services and procedures that replace much less

expensive services or procedures into a new technology APC to afford access to our beneficiaries.

Furthermore, we wish to clarify that we do not consider that merely being a different approach to an existing treatment or procedure qualifies a service for assignment to a new technology APC. As new approaches to existing procedures and services are adopted and performed, we expect the costs associated with these variations and improvements to be reflected in the claims data that we use to annually update the APC relative weights.

b. Criteria for Assignment to New Technology APC. In light of the experience we have gained over the past year in reviewing requests for new technology and transitional pass-through status, developing criteria to define new medical services and technologies under the inpatient PPS, and determining categories of new devices under the transitional pass-through provisions, we are proposing that the following criteria be used to determine whether a service be assigned to a new technology APC. These modifications are based on changes in data (we are no longer using 1996 data to set payment rates) and our continuing experience with the system of assigning new technology APCs.

- The service is one that could not have been adequately represented in the claims data being used for the most current annual payment update. (Current criterion based on 1996 data.)
- The service does not qualify for an additional payment under the transitional pass-through provisions. (This criterion is unchanged.)
- The service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs. We believe it is unnecessary to assign a new service to a new technology APC if it may be appropriately placed in a current APC.
- The service falls within the scope of Medicare benefits under section 1832(a) of the Act. (This criterion is unchanged.)
- The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. (This criterion is unchanged.)

We would delete the criterion that the service must have a HCPCS code. In the absence of an appropriate HCPCS code, we would consider creating a HCPCS code that describes the procedure or service. These HCPCS codes would be solely for hospitals to use when billing under the OPPS.

c. Revision of Application for New Technology Status. We also propose to change the information that interested parties must submit to have a service or procedure considered for assignment to a new technology APC. Based on our experience over the past year in reviewing new technology APC applications, we believe that the criteria would better assist us in determining eligibility for these APCs than do the current criteria. Specifically, to be considered, we propose to require that requests include the following information:

- The name by which the service is most commonly known. We currently require only the trade/brand name.
- A clinical vignette, including patient diagnoses that the service is intended to treat, the typical patient, and a description of what resources are used to furnish the service by both the facility and the physician. For example, for a surgical procedure this would include staff, operating room, and recovery room services as well as equipment, supplies, and devices, etc. This criterion would replace the criterion that requires a detailed description of the clinical application of the service. We believe we need a fuller description to help us understand how the service is furnished in hospitals.
- A list of any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA) and information to document receipt of FDA approval/clearances and the date obtained. This would be a refinement of the current requirement for demonstrating FDA approval.
- A description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location. This criterion and the one that follows would help inform our analysis by providing us with medical contacts.
- An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.
- Information about the clinical use and efficacy of the service such as peer-reviewed articles. Again, this criterion would assist us in our clinical review of the procedure.
- The CPT or HCPCS Level II code(s) that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under the OPPS. This criterion and the three that follow are refinements of the current HCPCS requirement.
- A list of the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. This list should include codes for all procedures and services that, if coded in addition to the code for the service under consideration for new technology status, would represent unbundling.
- A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.
- A proposal for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate. The proposal should include the reason why the service does not have a CPT or HCPCS Level II code, and why the CPT or HCPCS Level II code or codes currently used to describe the service are inadequate.
- An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc. (This criterion is unchanged.)
- The name, address, and telephone number of the party making the request. (This criterion is unchanged.)
- Other information as CMS may require to evaluate specific requests. (This criterion is unchanged.)

d. Length of Time in a New Technology APC. We are also proposing to change the period of time during which a service may be paid under a new technology APC. Although section 1833(t)(6)(B) of the Act, as amended by section 201 of BBRA 1999, sets a 2 to 3 year period of payment for transitional pass-through payments, this requirement does not extend to new technology APCs. In the April 7, 2000 final rule we stated our intention to adopt the same period of payment for new technology APCs for consistency. However, the experience we have gained during the first year of the OPPS has led us to the conclusion that a more flexible payment period would be preferable. Therefore, we are proposing to modify the time frame that we established for new technology APCs in the April 7, 2000 final rule and to retain a service within a new technology APC group until we have acquired adequate data that allow us to assign the service to a clinically appropriate APC. This would allow us to move a service from a new technology APC in less than 2 years if the data were available and would also allow us to retain a service in a new technology APC for more than 3 years if these data were not available.

We invite comment on the changes to the definition, criteria, application process, and timeframe that we are proposing for services and procedures that may qualify for assignment to a new technology APC under the OPPS.

VII. Transitional Pass-Through Payment Issues

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain innovative medical devices, drugs, and biologicals. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. Transitional pass-through payments are also required for new medical devices, drugs, and biologic agents that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payment for the procedures or services associated with the new device, drug, or biological. Under the statute, transitional pass-through payments are to be made for at least 2 years but not more than 3 years.

Section 402 of BIPA, which was enacted on December 21, 2000, made several changes to section 1833(t)(6) of the Act. First, section 1833(t)(6)(B)(i) of the Act, as amended, requires us to establish by April 1, 2001, initial categories to be used for purposes of determining which medical devices are eligible for transitional pass-through payments. We fulfilled this requirement through the issuance on March 22, 2001 of two Program Memoranda, Transmittals A–01–40 and A–01–41. These Program Memoranda can be found on the CMS homepage at *www.hcfa.gov/pubforms/transmit/A0140.pdf* and *www.hcfa.gov/pubforms/transmit/A0141.pdf,* respectively. We note that section 1833(t)(6)(B)(i)(II) of the Act explicitly authorizes the Secretary to establish initial categories by program memorandum.

Transmittal A–01–41 includes a list of the initial device categories and a crosswalk of all the item-specific C-codes for individual devices that were approved for transitional pass-through payments as of January 20, 2001 to the initial category code by which the device is to be billed beginning April 1, 2001.

Section 1833(t)(6)(B)(ii) of the Act also requires us to establish, through rulemaking, criteria that will be used to create additional categories, other than those established initially. The criteria for new categories are the subject of a separate interim final rule with comment period, which will be published at a later date.

Transitional pass-through categories are for devices only; they do not apply to drugs or biologicals. The regulations governing transitional pass-through payments for eligible drugs and biologicals remain unchanged. The process to apply for transitional pass-through payment for eligible drugs and biological agents, including radiopharmaceuticals, can be found in the April 7, 2000 **Federal Register** (65 FR 18481) and on the CMS web site at *http://www.hcfa.gov/medlearn/appdead.htm.* If we revise the application instructions in any way, we will post the revisions on our web site and submit the changes for the Office of Management and Budget (OMB) review under the Paperwork Reduction Act.

B. Discussion of Pro Rata Reduction

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a given year to an ''applicable percentage'' of projected total payments under the hospital OPPS. For a year before 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, the applicable percentage is specified by the Secretary up to 2.0 percent. If the Secretary estimates before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a (prospective) uniform reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded.

In order to prepare for making an estimate, we have constructed an extensive database that includes outpatient claims data submitted by hospitals for services furnished on or after July 1, 1999 and before July 1, 2000. We are also collecting device cost and utilization data that were provided by manufacturers. We are extracting device cost and utilization data from applications for pass-through status submitted by manufacturers, hospitals, specialty societies, and other entities. In their applications for pass-through status, manufacturers have supplied information on the expected cost to hospitals of devices and the procedures with which the devices are commonly used.

The information that we have collected thus far suggests that a significant pro rata reduction could be required for 2002 in order to meet the statutory limit on the amount of the pass-through payments. Given the potential magnitude of the reductions, we are reviewing our data and methodology to identify any flaws or weaknesses in them and to determine whether a significant reduction would actually be required under the statute. We are also considering the appropriateness of a number of possible alternative approaches to different technical aspects of estimating payments that would have the effect of minimizing the amount of any potential reduction in these payments. Below is a discussion of the methodology that we contemplate employing in developing our estimate.

We are considering a number of possible approaches to different technical aspects of estimating payments. As is always the case in making these types of estimates, it is necessary to make a number of assumptions in interpreting the data. We are tentatively contemplating using the following assumptions and techniques in developing our methodology:

1. Data and Methodology

We plan to base the estimate of 2002 pass-through expenditures on the claims we would use to set payment rates for 2002, 2001 pass-through amounts for drugs and radiopharmaceuticals, and device cost and use data from pass-through applications submitted by manufacturers, hospitals, specialty societies, and other entities. Projections to CY 2002 would employ price, volume, and service-mix inflators consistent with our baseline for OPPS spending. Estimates for drugs, radiopharmaceuticals, and devices would be made separately and combined for the final projection of pass-through spending.

2. Drugs and Biologicals

We would identify those drugs eligible for pass-through status that have been separately billed to the Medicare program on the claims that we intend to employ for the estimate. We would multiply the frequency of use for each of these drugs (that is, the number of line items multiplied by the number of units billed as shown in the claims data) by its 2001 pass-through payment amount. If any drugs are not reflected in the claims data, we would make an appropriate adjustment. Such an adjustment might take into account the extent to which the non-coded items are classified as orphan drugs and therefore would likely be used infrequently.

3. Radiopharmaceutical Drugs and Biological Products

Similar to the drug estimate, we would identify those

radiopharmaceuticals eligible for pass-through status that were separately billed to Medicare in the claims data file. We would estimate expenditures for these radiopharmaceuticals directly as described above. For radiopharmaceutical drugs, we would multiply the frequency of use for each item by the 2001 pass-through amount. We would estimate expenditures for the remaining items by using the frequency counts for all nuclear medicine procedures not billed with one of these radiopharmaceuticals.

4. Medical Devices

We would estimate the transitional pass-through payments attributable to devices by linking the frequencies for all device-related procedures in the claims data file with the cost and use data supplied by the manufacturers or other entities as part of their applications for pass-through status. We would match each device eligible as of January 2001 with the procedures with which it would be used. We would then calculate an average cost for each device or device package associated with a procedure.

The statute requires that we calculate transitional pass-through payments for devices by adjusting the hospital's charge for the device to cost and then subtracting an amount that reflects the device costs already included in the payment for the associated APC. As we explained in the April 7, 2000 final rule (65 FR 18481) we were not able to implement these subtractions at the time of implementation of the system. For 2001, as we explain in section III.C. of this preamble, we made these deductions for pacemakers and neurostimulators but not other devices because it was not feasible to make the deductions for the other devices at that time. As also explained in section III.C., we are proposing to make these subtractions for most other devices beginning in 2002. For the purpose of doing this estimation, we would deduct these amounts from each device package before multiplying that cost by the procedure frequencies. In total, we project the deductions to be $450 million. (See section III.C. for a discussion of how we calculated the deductions.)

5. Projecting to 2002

After making the three estimates as determined above, we plan to project prices and quantities in the estimates to 2002 using actuarial projections of price, volume, and service increase consistent with the OPPS baseline. We would add the three separate results for drugs, radiopharmaceuticals, and devices to determine an estimate of total pass-through spending.

A. Reducing Transitional Pass-Through Payments to Offset Costs Packaged Into APC Groups

1. Background

As discussed above in section II.C.1. of this preamble, in the November 13, 2000 interim final rule (65 FR 67806 and 67825), we explained that we originally excluded costs in revenue codes 274 (Prosthetic/orthotic devices), 275 (Pacemaker), and 278 (Other implants) from the calculation of APC payment rates because, before enactment of the BBRA 1999, we had proposed to pay for implantable devices outside of the OPPS and after the enactment of the BBRA, it was not feasible to revise our database to include these revenue codes in developing the April 7, 2000 final rule. We were able to make the necessary revisions and adjustments in time for implementation on January 1, 2001. When we packaged costs from these revenue codes to recalculate APC rates for 2001, to comply with the BBRA 1999 requirement, the median costs for a handful of procedures related to pacemakers and neurostimulators significantly increased. Therefore, we restructured the affected APCs to account for these changes in procedure level median costs.

Under section 1833(t)(6)(D)(ii) of the Act, as added by the BBRA 1999 and redesignated by BIPA, the amount of additional payment for an eligible device is the amount by which the hospital's cost exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. Thus, beginning January 1, 2001, for eligible devices, we deducted from transitional pass-through payments the dollar increase in the rates for the new APCs for procedures associated with the devices. Effective April 1, 2001, we revised our policy to subtract the dollar amount from the otherwise applicable pass-through payment for each category of device. The dollar amount subtracted in 2001 from transitional pass-through payments for affected categories of devices is as follows:

TABLE 4.—CY 2001 REDUCTIONS TO PASS-THROUGH PAYMENTS TO OFFSET DEVICE-RELATED COSTS PACKAGED IN ASSOCIATED APC GROUPS

For item billed under HCPCS code. * * *	Subtract from the pass-through payment the following amount:
C1767 Generator, neurostimulator (implantable)	$643.73
C1778 Lead, neurostimulator (implantable)	501.27
C1785 Pacemaker, dual chamber, rate-responsive (implantable)	2,843.00
C1786 Pacemaker, single chamber, rate-responsive (implantable)	2,843.00
C1816 Receiver and/or transmitter, neurostimulator (implantable)	537.83
C2619 Pacemaker, dual chamber, non rate-responsive (implantable)	2,843.00
C2620 Pacemaker, single chamber, non rate-responsive (implantable)	2,843.00

The increase in certain APC rates for device costs on January 1, 2001 was offset by the simultaneous reduction of the associated pass-through payments. Payments for the procedures in the affected APCs that did not include a pass-through device increased for 2001 and for procedures that did include devices, total payment for the procedure plus the device or devices did not change.

For 2002, in this proposed rule we are estimating the portion of each APC rate that could reasonably be attributed to the cost of associated devices that are eligible for pass-through payments. This amount will be deducted from the pass-through payments for those devices as required by the statute. Since the deductions to the pass-through payments for costs included in APCs for 2002 are included in the recalibration of the weights and the fixed pool of dollars for outpatient services, the total payment for the procedure plus device or devices will be reduced rather than remain constant as they did in 2001.

2. Proposed Reductions for 2002

First, we reviewed the APCs to determine which of them contained services that are associated with a category of devices eligible for a transitional pass-through payment. We then estimated the portion of the costs in those APCs that could reasonably be attributed to the cost of pass-through devices as follows:

• For each procedure associated with a pass-through device or devices, we examined all single-service bills (that is, bills that include services payable only under one APC) to determine utilization patterns for specific revenue centers that would reasonably be used for device-related charges in revenue codes 272 (sterile supplies), 275 (pacemakers), and 278 (other implants).

• We removed the costs in those revenue codes to calculate a cost for the bill net of device-related costs (reduced cost). For example, the average bill cost (in 1999–2000 dollars) for insertion of a cardiac pacemaker (CPT 33208) was $5,733. The average cost associated with revenue code 275 was $4,163, so the reduced cost for the procedure was $1,570. We calculated the ratio of the reduced cost ($1,570) to the full bill costs ($5,733), and we applied that ratio to the costs on any bills for CPT 33208 that did not use revenue code 275 to establish reduced cost at the procedure code level across all claims.

• To determine the reduced cost at the APC level and that portion of the APC payment rate associated with device costs, we calculated the median cost of the reduced cost bills for each relevant APC. For this calculation of the median, we allowed the full costs of bills for services in the APC that were not associated with pass-through devices.

• We calculated, for the APC, the percentage difference between the APC median of full cost or unreduced bills and the APC median where some or all of the bills had reduced costs. We applied this percent difference to the proposed APC payment rate in order to calculate the share of that rate attributable to the device or devices associated with procedures in the APC. In Table 5, we show the amount that we propose to subtract from the pass-through payment for an eligible device that is billed with the related APCs.

TABLE 5.—PROPOSED REDUCTION TO PASS-THROUGH PAYMENT TO OFFSET DEVICE-RELATED COSTS PACKAGED IN ASSOCIATED APC GROUPS

APC	Description	Percent differences	Device-related cost to be subtracted from pass-through payment for eligible device
00032	Insertion of Central Venous/Arterial Catheter	20.11	$73
00080	Diagnostic Cardiac Catheterization	9.99	164
00081	Non-Coronary Angioplasty or Atherectomy	27.06	303
00082	Coronary Atherectomy	6.95	462
00083	Coronary Angioplasty	19.85	506
00088	Thrombectomy	10.86	161
00089	Insertion/Replacement of Permanent Pacemaker and Electrodes	72.69	3,052
00090	Insertion/Replacement of Pacemaker Pulse Generator	77.13	2,877
00104	Transcatheter Placement of Intracoronary Stents	11.64	422
00106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	79.55	640
00107	Insertion of Cardioverter-Defibrillator	81.69	6,449
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	71.16	5,768
0122	Level II Tube Changes and Repositioning	24.92	72
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	7.35	61
0152	Percutaneous Biliary Endoscopic Procedures	12.05	107
0154	Hernia/Hydrocele Procedures	8.80	108
0182	Insertion of Penile Prosthesis	57.22	2,500
0185	Removal or Repair of Penile Prosthesis	56.82	1,652
0202	Level VIII Female Reproductive Procedures	25.02	503
0222	Implantation of Neurological Device	75.70	4,330
0223	Implantation of Pain Management Device	79.51	359
0225	Implantation of Neurotransmitter Electrodes	67.25	1,154
0227	Implantation of Drug Infusion Device	80.23	3,871
0229	Transcatheter Placement of Intravascular Shunts	35.46	1,083
0246	Cataract Procedures with IOL Insert	12.87	146

VIII. Conversion Factor Update for CY 2002

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis. Section 1833(t)(3)(C)(iv) of the Act, as redesignated by section 401 of the BIPA, provides that for 2002, the update is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act, reduced by one percentage point. Further, section 401 of the BIPA increased the conversion factor for 2001 to reflect an update equal to the full market basket percentage increase amount.

The most recent forecast of the hospital market basket increase for FY 2002 is 3.3 percent. To set the proposed OPPS conversion factor for 2002, we increased the 2001 conversion factor of $50.080, which reflects the BIPA provision of the full market basket update, by 2.3 percent, that is, the 3.3 percentage increase minus 1 percentage point.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the proposed conversion factor for 2002 to ensure that the revisions we are proposing to update the wage index are made on a budget-neutral basis. A budget neutrality factor of 0.9924 was calculated for wage index changes by comparing total payments from our simulation model using the proposed FY 2002 hospital inpatient PPS wage

index values to those payments using the current (FY 2001) wage index values.

The increase factor of 2.3 percent for 2002 and the required wage index budget neutrality adjustment of 0.9924 result in a proposed conversion factor for 2002 of $50.842.

IX. Summary of and Responses to MedPac Recommendations

The Medicare Payment Advisory Commission (MedPAC) offered several recommendations dealing with the OPPS in its March 2001 Report to Congress. Below we summarize each recommendation and respond to it.

MedPAC Recommendation: MedPAC has offered two recommendations regarding the update to the conversion factor in the OPPS. The first recommendation is that the Secretary should not use an expenditure target to update the conversion factor. The second recommendation is that Congress should require an annual update of the conversion factor in the OPPS that is based on the relevant factors influencing the costs of efficiently providing hospital outpatient care, and not just the change in input prices.

Response: Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor annually. Under section 1833(t)(3)(C)(iv) of the Act the update is equal to the hospital market basket percentage increase applicable under the hospital inpatient PPS, minus one percentage point for the years 2000 and 2002. The Secretary has the authority under section 1833(t)(3)(C)(iv) of the Act to substitute a market basket that is specific to hospital outpatient services. Finally, section 1833(t)(2)(F) of the Act requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient services, and section 1833(t)(9)(C) of the Act authorizes the Secretary to adjust the update to the conversion factor if the volume of services increased beyond the amount established under section 1833(t)(2)(F) of the Act.

In the September 8, 1998 proposed rule on the OPPS, we indicated that we were considering the option of developing an outpatient-specific market basket and invited comments on possible sources of data suitable for constructing one (63 FR 47579). We received no comments in response to this invitation, and we therefore announced in the April 7, 2000 final rule that we would update the conversion factor by the hospital inpatient market basket increase, minus one percentage point, for the years 2000, 2001, and 2002 (65 FR 18502). As required by section 401(c) of the BIPA, we made payment adjustments effective April 1, 2001 under a special payment rule that has had the effect of providing a full market basket update in 2001. We are, however, working with a contractor to study the option of developing an outpatient-specific market basket and would welcome comments and recommendations regarding appropriate data sources. We will also study the feasibility of developing appropriate adjustments for factors that influence the costs of efficiently providing hospital outpatient care, such as productivity increases and the introduction of new technologies, and the availability of appropriate sources of data for calculating the factors.

In the September 8, 1998 proposed rule on the OPPS, we proposed employing a modified version of the physicians' sustainable growth rate system (SGR) as an adjustment in the update framework to control for excess increases in the volume of covered outpatient services (63 FR 47586–47587). In response to comments on this proposal, we announced in the April 7, 2000 final rule that we had decided to delay implementation of a volume control mechanism, and to continue to study the options with a contractor (65 FR 18503). We will take MedPAC's recommendation into consideration in making a decision, and before implementing volume control mechanism we will publish a proposed rule with an opportunity for public comment.

MedPAC Recommendation: MedPAC recommends that the Secretary should develop formalized procedures in the OPPS for expeditiously assigning codes, updating relative weights, and investigating the need for service classification changes to recognize the costs of new and substantially improved technologies.

Response: Beginning with the April 7, 2000 final rule implementing the OPPS, we have outlined a comprehensive process to recognize the costs of new technology in the new system. One component of this process is the provision for pass-through payments for devices, drugs, and biologicals (see the discussion in conjunction with the next MedPAC recommendation). The other component is the creation of new APC groups to accommodate payment for new technology services that are not eligible for transitional pass-through payments. We assign new technology services that cannot be appropriately placed within existing APC groups to new technology APC groups, using costs alone (rather than costs plus clinical coherence) as the basis for the assignment. We describe revised criteria for assignment to a new technology group in section VI.G. of this preamble. When it is necessary, creation of new technology APC groups involves establishment of new codes. New codes are established through a well-ordered process that operates on an annual cycle. The cycle starts with submission of information by interested parties no later than April 1 of each year and ends with the announcement of new codes in October. As we stated previously, in the absence of an appropriate HCPCS code, we would consider creating a HCPCS code that describes the procedure or service. These codes would be solely for hospitals to use when billing under the OPPS.

We have also provided a mechanism for moving these services from the new technology APCs to clinically related APCs as part of the annual update of the APC groups. As described in section VI of this preamble, a service is retained within a new technology APC group until we have acquired adequate data that allow us to assign the service to an appropriate APC. We use the annual APC update cycle to assign the service to an existing APC that is similar both clinically and in terms of resource costs. If no such APC exists, we create a new APC for the service.

MedPAC Recommendation: MedPAC recommends that pass-through payments for specific technologies should be made in the OPPS only when a technology is new or substantially improved and adds substantially to the cost of care in an APC. MedPAC believes that the definition of ''new'' should not include items whose costs were included in the 1996 data used to set the OPPS payment rates.

Response: The statute requires that, under the OPPS, transitional pass-through payments are made for certain drugs, devices, and biologicals. The items designated by the statute to receive these pass-through payments include the following:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.
- Current drugs and biologicals used for the treatment of cancer, and brachytherapy and temperature monitored cryoablation devices used for the treatment of cancer.
- Current radiopharmaceutical drugs and biologicals.
- New drugs and biologicals in instances in which the item was not being paid as a hospital outpatient service as of December 31, 1996, and when the cost of the item is ''not insignificant'' in relation to the OPPS payment amount.
- Effective April 1, 2001, categories of Medical devices when the cost of the

category is not insignificant'' in relation to the OPPS payment amount.

We are publishing a separate interim final rule in which we lay out the criteria for establishing categories of devices eligible for pass-through payments.

Section 1833(t)(6) of the Act provides that once a category is established, a specific device may receive a pass-through payment for 2 to 3 years if the device is described by an existing category, regardless of whether it was being paid as a hospital outpatient service as of December 31, 1996 or its cost meets the ''not insignificant'' criterion. Thus, the statute allows for certain devices that do not meet MedPAC's recommended limitation on a ''new'' device to receive transitional pass-through payments. However, no categories are created on the basis of devices that were paid for on or before December 31, 1996. That is, while devices paid for on or before December 31, 1996 can be included in a category, we would establish a category only on the basis of devices that were not being paid as hospital outpatient services as of December 31, 1996.

MedPAC Recommendation: MedPAC recommends that pass-through payments for specific technologies in the OPPS should be made on a budget-neutral basis and that the costs of new or substantially improved technologies should be factored into the update of the outpatient conversion factor.

Response: The statute requires that the transitional pass-through payments for drugs, devices, and biologicals be made on a budget neutral basis. Estimated pass-through payments are limited under the statute to 2.5 percent (and up to 2.0 percent for 2004 and thereafter) of estimated total program payments for covered hospital outpatient services. We adjust the conversion factor to account for the proportion of total program payments for covered hospital outpatient services, up to the statutory limit, that we estimate will be made in pass-through payments. As we have discussed in response to MedPAC's recommendation concerning an update framework for the OPPS conversion factor, we will study the feasibility of including appropriate adjustments for factors, including introduction of new technologies, that influence the costs of efficiently providing hospital outpatient care within such a framework.

MedPAC Recommendation: MedPAC recommends that the Congress should continue the reduction in outpatient coinsurance to achieve a 20 percent coinsurance rate by 2010.

Response: For most services that Medicare covers, the program is responsible for 80 percent of the total payment amount, and beneficiaries pay 20 percent. However, under the cost-based payment system in place for outpatient services before the OPPS, beneficiaries paid 20 percent of the hospital's charges for these services. As a result, coinsurance was often more than 20 percent of the total payment amount for the services.

The BBA established a formula under the OPPS that was designed to reduce coinsurance gradually to 20 percent of the total payment amount. Under this formula, a national copayment amount was set for each service category, and that amount is to remain frozen as payment rates increase until the coinsurance percentage falls to 20 percent for all services. On average, beneficiaries have paid about 16 percent less in copayments for hospital outpatient services during 2000 under the OPPS than they would have paid under the previous system. However, it is true that the coinsurance remains higher than 20 percent of the Medicare payment amount for many services.

Subsequent legislation has placed caps on the coinsurance percentages to speed up this process. Specifically, section 111 of BIPA amended section 1833(t)(8)(C)(ii) of the Act to reduce beneficiary coinsurance liability by phasing in a cap on the coinsurance percentage for each service. Starting on April 1, 2001, coinsurance for a single service furnished in 2001 cannot exceed 57 percent of the total payment amount for the service. The cap will be 55 percent in 2002 and 2003, and will be reduced by 5 percentage points each year from 2004 to 2006 until coinsurance is limited to 40 percent of the total payment for each service. The underlying process for decreasing coinsurance will also continue during this period (see discussion in section IV.A. of this preamble). However, MedPAC projects that under current law, it would take until 2029 to reach the goal of 20 percent coinsurance for all services.

We agree with MedPAC's goal of continuing the reduction in outpatient coinsurance, and we would welcome enactment of a practical measure to do so.

X. Provider-Based Issues

A. Background and April 7, 2000 Regulations

On April 7, 2000, we published a final rule specifying the criteria that must be met for a determination regarding provider-based status (65 FR 18504). Since the beginning of the Medicare program, some providers, which we refer to as ''main providers,'' have functioned as a single entity while owning and operating multiple departments, locations, and facilities. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments for services furnished at the provider-based facility, and may also increase the coinsurance liability of Medicare for those services.

The regulations at § 413.65 define provider-based status as ''the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.'' Section 413.65(b)(2) states that before a main provider may bill for services of a facility as if the facility is provider-based, or before it includes costs of those services on its cost report, the facility must meet the criteria listed in the regulations at § 413.65(d). Among these criteria are the requirements that the main provider and the facility must have common licensure (when appropriate), the facility must operate under the ownership and control of the main provider, and the facility must be located in the immediate vicinity of the main provider.

The effective date of these regulations was originally set at October 10, 2000, but was subsequently delayed and is now in effect for cost reporting periods beginning on or after January 10, 2001. Program instructions on provider-based status issued prior to that date, found in Section 2446 of the Provider Reimbursement Manual—Part 1 (PRM–1), Section 2004 of the Medicare State Operations Manual (SOM), and CMS Program Memorandum (PM) A–99–24, will apply to any facility for periods before the new regulations become applicable to it. (Some of these instructions will not be applied because they have been superseded by specific legislation on provider-based status, as described in item C below).

B. Provider-Based Issues/Frequently Asked Questions

Following publication of the April 7, 2000 final rule, we received many requests for clarification of policies on specific issues related to provider-based status. In response, we published a list of ''Frequently Asked Questions'' and the answers to them on the CMS web site at *www.hcfa.gov/medlearn/provqa.htm.* (This document can also be obtained by contacting the CMS (Formerly, HCFA) Regional Office.)

These Qs and As did not revise the regulatory criteria, but do provide subregulatory guidance for their implementation.

C. Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)

On December 21 2000, the Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554) was enacted. Section 404 of BIPA contains provisions that significantly affect the provider-based regulations at § 413.65. Section 404 includes a grandfathering provision for facilities treated as provider-based on October 1, 2000; alternative criteria for meeting the geographic location requirement; and criteria for temporary treatment as provider-based.

1. Two-Year ''Grandfathering''

Under section 404(a) of BIPA, any facilities or organizations that were ''treated'' as provider-based in relation to any hospital or CAH on October 1, 2000 will continue to be treated as such until October 1, 2002. For the purpose of this provision, we interpret ''treated as provider-based'' to include those facilities with formal CMS determinations, as well as those facilities without formal CMS determinations that were being paid as provider-based as of October 1, 2000. As a result, existing provider-based facilities and organizations may retain that status without meeting the criteria in the regulations under §§ 413.65(d), (e), (f), and (h) until October 1, 2002. These provisions concern provider-based status requirements, joint ventures, management contracts, and services under arrangement. Thus, the provider-based facilities and organizations affected under section 404(a) are not required to submit an application for or obtain a provider-based status determination in order to continue receiving reimbursement as provider-based during this period.

These provider-based facilities and organizations will not be exempt from the Emergency Medical Treatment and Active Labor Act (EMTALA) requirements for provider-based facilities and organizations (revised § 489.24(b) and new § 489.24(i)) or from the obligations of hospital outpatient departments and hospital-based entities in § 413.65(g), such as the requirement that off-campus facilities provide written notices to Medicare beneficiaries of coinsurance liability. These requirements become effective for hospitals on the first day of the hospital's cost reporting period beginning on or after January 10, 2001.

We are aware that many hospitals and physicians continue to have significant concerns with our policy on the applicability of EMTALA to provider-based facilities and organizations. We intend to re-examine these regulations and, in particular, reconsider the appropriateness of applying EMTALA to off-campus locations. At the same time, we want to assure that those departments that Medicare pays as hospital-based departments are appropriately integrated with the hospital as a whole. We intend to publish a proposed rule to address these issues more fully.

2. Geographic Location Criteria

Section 404(b) of BIPA provides that those facilities or organizations that are not included in the grandfathering provision at section 404(a) are deemed to comply with the ''immediate vicinity'' requirements of the new regulations under § 413.65(d)(7) if they are located not more than 35 miles from the main campus of the hospital or critical access hospital. Therefore, those facilities located within 35 miles of the main provider satisfy the immediate vicinity requirement as an alternative to meeting the ''75/75 test'' under § 413.65(d)(7).

In addition, BIPA provides that certain facilities or organizations are deemed to comply with the requirements for geographic proximity (either the ''75/75 test'' or the ''35-mile test'') if they are owned and operated by a main provider that is a hospital with a disproportionate share adjustment percentage greater than 11.75 percent and is (1) owned or operated by a unit of State or local government, (2) a public or private nonprofit corporation that is formally granted governmental powers by a unit of State or local government, or (3) a private hospital that has a contract with a state or local government that includes the operation of clinics of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare or Medicaid.

These geographic location criteria are permanent. While those facilities or organizations treated as provider-based on October 1, 2000 are covered by the two-year grandfathering provision noted above, the geographic location criteria at section 404(b) of BIPA and the regulations at § 413.65(d)(7) will apply to facilities or organizations not treated as provider-based as of that date, effective with the hospital's cost reporting period beginning on or after January 10, 2001. Beginning October 1, 2002, these criteria will also apply to the grandfathered facilities.

3. Criteria for Temporary Treatment as Provider-Based

Finally, section 404(c) of BIPA also provides that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000 and before October 1, 2002 may not be treated as not having provider-based status for any period before a determination is made. Thus, recovery for overpayments will not be made retroactively for noncompliance with the provider-based criteria once a request for a determination during that time period has been made. For hospitals that do not qualify for grandfathering under section 404(a), until a uniform application is available, a request for provider-based status should be submitted to the appropriate CMS Regional Office (RO). At a minimum, the request should include the identity of the main provider and the facility or organization for which provider-based status is being sought and supporting documentation to demonstrate compliance with the provider-based status criteria in effect at the time the application is submitted. Once such a request has been submitted on or after October 1, 2000, and before October 1, 2002, CMS will treat the facility or organization as being provider-based from the date it began operating as provider-based (as long as that date is on or after October 1, 2000) until the effective date of a CMS determination that the facility or organization is not provider-based.

Facilities requesting a provider-based status determination on or after October 1, 2002 will not be covered by the provision concerning temporary treatment as provider-based in section 404(c) of BIPA. Thus, as stated in § 413.65(n), CMS ROs will make provider-based status applicable as of the earliest date on which a request for determination has been made and all requirements for provider-based status in effect as of the date of the request are shown to have been met, not on the date of the formal CMS determination. If a facility or organization does not qualify for provider-based status and CMS learns that the provider has treated the facility or organization as provider-based without having obtained a provider-based determination under applicable regulations, CMS will review all payments and may seek recovery for overpayments in accordance with the regulations at § 413.65(j), including overpayments made for the period of time between submission of the request or application for provider-based status and the issuance of a formal CMS determination.

D. Proposed Changes to Provider-Based Regulations

To fully implement the provisions of section 404 of BIPA and to codify the clarifications currently stated only in the Q&As on provider-based status, as described above, we are proposing to revise the regulations as follows.

1. Clarification of Requirements for Adequate Cost Data and Cost Finding (§ 413.24(d))

As part of the April 7, 2000, final rule implementing the prospective payment system for hospital outpatient services to Medicare beneficiaries, under § 413.24, Adequate Cost Data and Cost Finding, we added a new paragraph (d)(6), entitled ''Management Contracts.'' Since publication of the final rule, we have received several questions concerning the new paragraph.

In response to these questions, we are proposing changes in wording to clarify the meaning of that paragraph. In addition, for further clarity, we are revising the coding and title of that material. Under our proposal, § 413.24(d)(6)(i) would become § 413.24(d)(6) and § 413.24(d)(6)(ii) would become § 413.24(d)(7). As revised, paragraph (d)(6) would address the situation when the main provider in a provider-based complex purchases services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Therefore, where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the provider cannot be separately identified, the costs of the services purchased through a contract for the provider-based entity or provider department must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

For costs of services furnished to free-standing entities, we would also clarify in revised § 413.24(d)(7), that the costs that a provider incurs to furnish services to free-standing entities with which it is associated are not allowable costs of that provider. Any costs of services furnished to a free-standing entity must be identified and eliminated from the allowable costs of the servicing provider, to prevent Medicare payment to that provider for those costs. This may be done by including the free-standing entity on the cost report as a nonreimbursable cost center for the purpose of allocating overhead costs to that entity. If this method would not result in an accurate allocation of costs to the entity, the provider must develop detailed work papers showing how the cost of services furnished by the provider to the entity were determined. These costs are removed from the applicable cost centers of the servicing provider.

This revision is not a change in the policy, but instead is a clarification to the policy set forth in the April 7, 2000 final rule.

2. Scope and Definitions (§ 413.65(a))

In Q/A 9 published on the CMS (Formerly, HCFA) web site at *www.hcfa.gov/medlearn/provqa.htm*, we identified specific types of facilities for which provider-based determinations would not be made, since their status would not affect either Medicare payment levels or beneficiary liability. (This document may also be obtained by contacting the CMS (Formerly, HCFA) Regional Office.) The facilities identified in Q/A 9 are ambulatory Surgical Centers (ASCs), comprehensive outpatient rehabilitation facilities (CORFs); home health agencies (HHAs); skilled nursing facilities (SNFs); hospices; inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services; independent diagnostic testing facilities and any other facilities that furnish only clinical diagnostic laboratory tests; facilities furnishing only physical, occupational or speech therapy to ambulatory patients, for as long as the $1500 annual cap on coverage of physical, occupational, and speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation; and end-stage renal disease (ESRD) facilities. Determinations for ESRD facilities are made under § 413.174.

We propose to revise the regulations at § 413.65(a) to clarify that these facilities are not subject to the provider-based requirements and that provider-based determinations will not be made for them.

3. BIPA Provisions on Grandfathering and Temporary Treatment as Provider-Based (§§ 413.65(b)(2) and (b)(5))

Current regulations at § 413.65(b)(2) state that a main provider or a facility must contact CMS (Formerly, HCFA) and the facility must be determined by CMS (Formerly, HCFA) to be provider-based before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report. However, as explained earlier, sections 404(a) and (c) of BIPA require that certain facilities be grandfathered for a 2-year period, and that facilities applying between October 1, 2000 and October 1, 2002 for provider-based status with respect to a hospital be given provider-based status on a temporary basis, pending a decision on their applications. To implement these provisions, we propose to revise the regulations in § 413.65(b)(2) to state that if a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until October 1, 2002, and the requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), and (h) of § 413.65 will not apply to that hospital or CAH with respect to that facility until October 1, 2002. We would further state that for purposes of paragraph (b)(2), a facility will be considered to have been treated as provider-based on October 1, 2000, if on that date it either had a written determination from CMS (Formerly, HCFA) that it was provider-based as of that date, or was billing and being paid as a provider-based department or entity of the hospital.

We would also propose to add a new § 413.65(b)(2) to state that a facility for which a determination of provider-based status in relation to a hospital or CAH is requested on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS (Formerly, HCFA) determines that the facility does not qualify for provider-based status.

4. Reporting (§ 413.65(c)(1))

Current regulations at § 413.65(c) state that a main provider that creates or acquires a facility or organization for which it wishes to claim provider-based

status, including any physician offices that a hospital wishes to operate as a hospital outpatient department or clinic, must report its acquisition of the facility or organization to CMS (Formerly, HCFA) if the facility or organization is located off the campus of the provider, or inclusion of the costs of the facility or organization in the provider's cost report would increase the total costs on the provider's cost report by at least 5 percent, and must furnish all information needed for a determination as to whether the facility or organization meets the requirements in paragraph (d) of this section for provider-based status. Concern has been expressed that such reporting would duplicate the requirement for obtaining approval of a facility as provider-based before billing its services that way or including its costs on the cost report of the main provider (current § 413.65(b)(2)). To prevent any unnecessary duplicate reporting, we propose to delete the current requirement from § 413.65(c)(1). We would, however, retain the requirement that a main provider that has had one or more facilities considered provider-based also report to CMS (Formerly, HCFA) any material change in the relationship between it and any provider-based facility, such as a change in ownership of the facility or entry into a new or different management contract that could affect the provider-based status of the facility.

5. Geographic Location Criteria (§ 413.65(d)(7))

As explained earlier in C.2 of this section, section 404(b) of BIPA mandates that facilities seeking provider-based status be considered to meet any geographic location criteria if they are located not more than 35 miles from the main campus of the hospital or CAH to which they wish to be based, or meet other specific criteria relating to their ownership and operation. To implement this provision, we propose to revise § 413.65(d)(7) to state that facility will meet provider-based location criteria if it and the main provider are located on the same campus, or if one of the following three criteria are met:

- The facility or organization is located within a 35-mile radius of the main campus of the hospital or CAH that is the potential main provider;
- The facility or organization is owned and operated by a hospital or CAH that—

(A) Is owned or operated by a unit of State or local government;

(B) Is a public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or,

(C) Is a private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services to low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan); and

(D) Has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act.

- The facility meets the criteria currently set forth in § 413.65(d)(7)(i) for service to the same patient population as the main provider.

6. Notice to Beneficiaries of Coinsurance Liability (§ 413.65(g)(7))

Current regulations at § 413.65(g)(7) state that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, the hospital has a duty to provide written notice to the beneficiary, prior to the delivery of services, of the amount of the beneficiary's potential financial liability (that is, of the fact that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability). The notice must be one that the beneficiary can read and understand.

Some concern had been expressed that providing notice of a beneficiary's exact liability might be difficult in cases where the treating physician was in the process of diagnosing the patient's condition and was unsure of exactly what services might be required. In response to this concern we clarified in the preamble to an interim final rule with comment period published on August 3, 2000 (65 FR 47670) that if the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains the fact that the beneficiary will incur a coinsurance liability to the hospital that they would not incur if the facility were not provider-based. The interim final rule preamble § 413.65(g)(7)) further explained that the hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital. If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, prior to the delivery of services, to the beneficiary's authorized representative.

We are proposing to amend § 413.65(g)(7) to include this clarifying language.

7. Clarification of Protocols for Off-Campus Departments (§ 489.24(i)(2)(ii))

Current regulations at § 489.24(i) specify the antipatient dumping obligations that hospitals have with respect to individuals who come to off-campus hospital departments for the examination or treatment of a potential emergency medical conditions. These obligations are sometimes known as EMTALA obligations, after the Emergency Medical Treatment and Active Labor Act, which is the legislation that first imposed the obligations. Currently, hospitals are responsible for ensuring that personnel at their off-campus departments are trained and given appropriate protocols for the handling of emergency cases.

In the case of off-campus departments not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus before arranging an appropriate transfer to a medical facility other than the main hospital.

Some concern had been expressed that taking the time needed to make such contacts might inappropriately delay the appropriate transfer of emergency patients in cases where the patient's condition was deteriorating rapidly. In response to this concern we clarified in the preamble to the interim final rule with comment period published on August 3, 2000 cited above (65 FR 47670) that in any case of the kind described in § 489.24(i)(2)(ii) the contact with emergency personnel at the main hospital campus should be made either concurrently with or after the actions needed to arrange an appropriate transfer, if doing otherwise would significantly jeopardize the individual's life or health. This does not relieve the off-campus department of the responsibility for making the contact, but only clarifies that the contact may be delayed in specific cases where doing otherwise would endanger a patient subject to EMTALA protection.

We are proposing to amend § 489.24(i)(2)(ii) to include this clarifying language.

8. Other Changes

In addition to the changes cited above, we are proposing to make the following conforming and clarifying changes:

• We are correcting date references in §§ 413.65(i)(1)(i) and (i)(2), in order to take into account the effective date of the current regulations.

• We are substituting ''CMS'' for ''HCFA'' throughout the revised sections of part 413, to reflect the renaming of the Health Care Financing Administration (HCFA) as the Centers for Medicare & Medicaid Services (CMS).

XI. Summary of Proposed Changes for 2002

A. Changes Required by BIPA 2000

We are proposing the following changes to the OPPS, to implement the provisions of BIPA 2000:

• Limit coinsurance to a specified percentage of APC payment amounts.

• Provide hold-harmless transitional corridor payments to children's hospitals.

• Provide separate APCs for services that use contrast agents and those that do not.

• Pay for glaucoma screening as a covered service.

• Pay for certain new technology used in screening and diagnostic mammograms.

B. Additional Changes

We are proposing the following additional changes to the OPPS:

• Add APCs, delete APCs, and modify the composition of services within some existing APCs.

• Add an APC group that would provide payment for observation services in limited circumstances to patients having specific diagnoses.

• Recalibrate the relative payment weights of the APCs.

• Update the conversion factor and wage index.

• Revise the APC payment amounts to reflect the APC reclassifications, the recalibration of payment weights and the other required updates and adjustments.

• Make reductions in pass-through payments for specific drugs and categories of devices to account for the drug and device costs that are included in the APC payment for associated procedures and services.

• Apply a standard procedure to calculate copayment amounts when new APCs are created or when APC payment rates are increased or decreased as a result of recalibrated weights.

• Calculate outlier payments on a service-by-service basis beginning in 2002. We also propose a methodology for allocating packaged services to individual APCs in determining costs of a service and we propose to use a hospital's overall outpatient cost-to-charge ratio to convert charges to costs.

• Change the threshold for outlier payments to require costs to exceed 3 times the APC payment amount, and pay 50 percent of any excess costs above the threshold as an outlier payment.

• Exclude hospitals located outside the 50 states, the District of Columbia and Puerto Rico from the OPPS.

• Exclude from payment under the OPPS certain services that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

• Exclude from the OPPS certain items and services (for example, bad debts, direct medical education and certain certified registered nurse anesthetists services) that are paid on a cost basis.

• Propose to update the payments for pass-through radiopharmaceuticals, drugs, and biologicals on a calendar year basis to reflect increases in AWP.

• Allow reprocessed single use devices to be considered eligible for pass-through payments if the reprocessing process for single use devices meets the FDA's most recent criteria.

• Revise the criteria we will use to determine whether a procedure or service is eligible to be assigned to a new technology APC.

• Revise the list of information that must be submitted to request assignment of a service or procedure to a new technology APC.

• Provide more flexibility in the amount of time a service may be paid under a new technology APC.

C. Technical Corrections

We are proposing to make conforming changes to the regulations in 42 CFR parts 413, 419 and 489.

In part 413 we would—

• Revise § 413.24(d)(6) and (d) (7) to clarify requirements for adequate cost data and cost findings and clarify the meaning of the paragraph.

• Revise § 413.65(a)(1) to clarify the specified types of facilities identified in this section that are not subject to the provider-based requirements and that provider-based determinations will not be made for them.

• Revise the definition of ''Provider-based entity'' in § 413.65(a)(2).

• Revise § 413.65(b) to implement the BIPA provisions on grandfathering and temporary treatment of a facility as provider-based.

• Delete the existing requirement in § 413.65(c)(1) in order to prevent unnecessary duplicate reporting.

• Specify in § 413.65(d)(7) that a facility will meet provider-based geographic location criteria if it and the main provider are located on the same campus, or if a facility meets one of the three criteria specified in this paragraph.

• Clarify in § 413.65(g)(7) that the hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

• Correct date references in §§ 413.65(i)(1)(ii) and (i)(2), in order to take into account the effective date of the current regulations.

In part 419, we would—

• Revise § 419.2 to clarify the costs that are excluded from the OPPS rates.

• Revise the reference to the effective date of the OPPS to August 1, 2000 in § 419.20(a).

• Add new §§ 419.20(b)(3) and (b)(4) to specify that a hospital located outside one of the 50 States, the District of Columbia, or Puerto Rico, or a hospital of the Indian Health Service is excluded from the hospital outpatient prospective payment system.

• Add a new § 419.22(r) to specify that services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatients services under Medicare Part B are not paid for under the hospital OPPS.

• Revise § 419.32 to reflect the revised update to the payment rates, as required by section 401 of BIPA.

• Replace the word ''coinsurance'' each time it appears in §§ 419.40, 419.41, 419.42 and 419.43 with the word ''copayment.''

• Redesignate existing § 419.41(c)(4)(ii) as paragraph (c)(4)(iv), and add paragraphs (c)(4)(ii) and (c)(4)(iii) to include the provisions of section 1833(t)(8)(C)(ii) of the Act. This section would specify that, effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective rate for that APC and the national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar year 2004, 45 percent in calendar year 2005, and 40 percent in calendar year 2006 and thereafter.

• Revise § 419.70(d) to give children's hospitals the same permanent hold harmless protection as cancer hospitals under the OPPS, as required by section 405 of BIPA.

• Revise § 489.24(i)(2)(ii) to clarify that, for the purposes of arranging an appropriate transfer of a patient from an off-campus department, staff at the off-campus department may delay contacting the emergency personnel at the main hospital campus in the specific cases where doing otherwise would endanger a patient.

XII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Sections 413.65 and 419.42 of this proposed regulation contain information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995. However, §§ 413.65 and 419.42 have been approved by OMB under approval number 0938–0798, with a current expiration date of August 31, 2003 and OMB approval number 0938–0802, with a current expiration date of August 31, 2001.

XIII. Response to Public Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments concerning the provisions of this proposed rule that we receive by the date and time specified in the **DATES** section of this preamble and respond to those comments in the preamble to that rule.

Modification of 60-day Comment Period

The highly complex analysis surrounding the possibility of a significant pro rata reduction has caused a delay in the publication of the proposed rule. It is essential for this rule to become effective by January 1, 2002 for hospital outpatient departments to receive appropriate higher payments and to ensure that beneficiaries receive the benefits of further reductions in beneficiary copayments. Congress has directed us to update payment rates annually, at the beginning of each calendar year. If the increased provider payments and reduced beneficiary copayments do not become effective by the statutory effective date of January 1, 2002, enormous uncertainty and administrative difficulties will result for beneficiaries, providers, and intermediaries. In addition, any delay in receiving increased provider payments or reduced beneficiary copayments will cause harm to providers and beneficiaries. Consequently, in order to avoid imposing this uncertainty and harm on beneficiaries, providers, and intermediaries and to meet the January 1, 2002 statutory effective date for the update to the OPPS payment rates, we find we must shorten the comment period to 40 days. For the reasons discussed above, we find there is good cause to modify the 60-day comment period. We further find that this comment cycle will give parties sufficient opportunity to comment adequately on our proposed rule. In addition, we are immediately posting this proposed rule on our website at http://www.hcfa.gov/regs/cms1159p.htm pending publication in the **Federal Register** to ensure the maximum possible opportunity for public comment.

XIV. Regulatory Impact Analysis

A. General

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually).

The statutory effects of the provisions that would be implemented by this proposed rule result in expenditures exceeding $100 million per year. We estimate the total impact of these changes for CY 2002 payments compared to CY 2001 payments to be approximately a $450 million increase. Therefore, this proposed rule is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status of by having revenues of $5 to $25 million or less annually (see 65 FR 69432). For purposes of the RFA, all providers of hospital outpatient services are considered small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds, or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the OPPS, we classify these hospitals as urban hospitals.

It is clear that the changes in this proposed rule would affect both a substantial number of rural hospitals as well as other classes of hospitals, and the effects on some may be significant. Therefore, the discussion below, in combination with the rest of this proposed rule, constitutes a regulatory impact analysis.

Section 202 of the Unfunded Mandate Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This proposed rule would not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed

rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have any negative impact on the rights, roles, and responsibilities of State, local or tribal governments.

B. Changes in This Proposed Rule

We are proposing several changes to the OPPS that are required by the statute. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We are also required under section 1833(t)(8)(A) of the Act to revise, not less often than annually, the wage index and other adjustments. In addition, we must review the clinical integrity of payment groups and weights at least annually. Accordingly, in this proposed rule, we are updating the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2002. We are also proposing revisions to the relative APC payment weights based on claims data from July 1, 1999 through June 30, 2000. Finally, we are proposing to begin calculating outlier payments on an APC-specific basis rather than the current method of calculating outlier payments for each claim.

The projected aggregate impact of updating the conversion factor is to increase total payments to hospitals by 2.3 percent. As described in the preamble, budget neutrality adjustments are made to the conversion factor and the weights to assure that the revisions in the wage index, APC groups, and relative weights do not affect aggregate payments. In addition, the determination of the parameters for outlier payments have been modified so that projected outlier payments for 2002 are equivalent to the established policy target of 2.0 percent of total payments. Because we are not revising the target percentage, there is no estimated aggregate impact from modifying the method of determining outlier payments.

The impact of the wage, recalibration and outlier changes do vary somewhat by hospital group. Estimates of these impacts are displayed on Table 6.

C. Limitations of Our Analysis

The distributional impacts represent the projected effects of the proposed policy changes, as well as statutory changes effective for 2002, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per service while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service mix, or number of encounters.

D. Estimated Impacts of This Proposed Rule

Column 5 in Table 6 represents the full impact on each hospital group of all the changes for 2002. Columns 2 through 4 in the table reflect the independent effects of the proposed change in the wage index, the APC reclassification and recalibration changes and the change in outlier method, respectively.

In general, the wage index changes favor rural hospitals, particularly the largest in bed size and volume. The only rural hospitals that would experience a negative impact due to wage index changes are those in the Middle Atlantic and Pacific Regions, a decrease of 0.3 percent for each. Conversely, the urban hospitals are generally negatively affected by these changes, with the largest effect on those with 500 or more beds (0.6 percent decrease) and those in the Middle Atlantic (1.7 percent decrease) and West South Central Regions (1.5 percent decrease).

We estimate that the APC reclassification and recalibration changes have generally an opposite impact from the wage index, causing increases for all urban hospitals except those with under 200 beds and volumes of fewer than 21,000 services per year and those located in the New England (a 0.1 percent decrease), Middle Atlantic (a 0.7 percent decrease), East North Central (a 0.55 percent decrease), and Puerto Rico (a 5.6 percent decrease) Regions.

The change in outlier policy to an APC-specific payment has a slight negative effect on rural hospitals as a group (a 0.2 percent decrease), no effect on urban hospitals as a group, and slight negative effects on all smaller hospitals as well as those with lower volumes of services.

The overall projected increase in payments for urban hospitals is slightly greater (2.4 percent) than the average increase for all hospitals while the increase for rural hospitals is somewhat less than the average increase (1.9 percent). Rural hospitals gain 1.2 percent from the wage index change, but lose a combined 1.7 percent from the APC changes and the change in method of determining outlier payments.

In both urban and rural areas, hospitals that provide a higher volume of outpatient services are projected to receive a larger increase in payments than lower volume hospitals. In rural areas, hospitals with volumes of fewer than 5000 services are projected to experience a small decline in payments (−0.1 percent). The less favorable impact for the low volume hospitals is attributable to the APC changes and the change in outlier method. For example, rural hospitals providing fewer than 5000 services are projected to lose a combined 3 percent due to these changes.

Urban hospitals in the Middle Atlantic region are projected to receive no increase in payments, and we estimate a decline of 0.1 percent for rural hospitals in this region. Both the urban and rural hospitals lose 2.4 percent due to the wage index change and APC changes. The urban hospitals are affected more by the wage index change (−1.7 percent), while rural hospitals are affected more by the recalibration (−2.1 percent). Urban hospitals in the East South Central Region are projected to experience the largest increase in payments (5.5 percent).

Major teaching hospitals are projected to experience a smaller increase in payments (1.3 percent) than the aggregate for all hospitals due to negative impacts of the wage index (−0.7 percent), recalibration (−0.1 percent), and outlier changes (−0.2 percent). Hospitals with less intensive teaching programs are projected to experience an overall increase (3.0 percent) that is larger than the average for all hospitals. This is attributable to the fact that there is no impact on this group for the wage index change and positive impacts for both the APC changes (0.6 percent) and outlier changes (0.1). There is little difference in impact among hospitals with varying shares of low-income patients.

TABLE 6.—IMPACT OF CHANGES FOR CY 2002 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

[Percent changes in total payments (program and beneficiary)]

	Number of hospitals [1] (1)	New wage index [2] (2)	APC recalib. [3] (3)	New outlier policy [4] (4)	All CY 2002 changes [5] (5)
ALL HOSPITALS	5,077	0.0	0.0	0.0	2.3
NON–TEFRA HOSPITALS	4,701	0.0	0.0	0.0	2.3
URBAN HOSPS	2,608	−0.3	0.4	0.0	2.4
LARGE URBAN (GT 1 MILL.)	1,495	−0.5	0.1	0.0	1.9
OTHER URBAN (LE 1 MILL.)	1,113	−0.1	0.7	0.1	3.1
RURAL HOSPS	2,093	1.2	−1.5	−0.2	1.9
BEDS (URBAN):					
0–99 BEDS	661	0.0	−1.9	−0.1	0.3
100–199 BEDS	918	−0.3	−0.4	0.1	1.8
200–299 BEDS	510	−0.3	0.6	0.0	2.6
300–499 BEDS	374	−0.3	1.1	0.1	3.2
500 + BEDS	145	−0.6	1.1	0.0	2.7
BEDS (RURAL):					
0—49 BEDS	1,249	0.4	−2.4	−0.6	−0.2
50–99 BEDS	506	0.7	−2.2	−0.2	0.6
100–149 BEDS	198	1.6	−0.7	0.0	3.2
150–199 BEDS	74	1.6	−1.0	−0.1	2.8
200 + BEDS	66	2.6	−0.2	0.1	4.8
VOLUME (URBAN):					
LT 5,000	363	−0.5	−0.5	−0.3	1.0
5,000–10,999	496	−0.3	−1.1	0.0	0.9
11,000–20,999	605	−0.4	−0.4	0.1	1.7
21,000–42,999	746	−0.4	0.6	0.1	2.6
GT 42,999	398	−0.2	0.6	0.0	2.7
VOLUME (RURAL):					
LT 5,000	1,000	0.4	−2.0	−1.0	−0.1
5,000–10,999	569	0.5	−2.3	−0.2	0.2
11,000–20,999	322	1.1	−1.7	−0.1	1.6
21,000–42,999	171	1.7	−0.9	0.0	3.0
GT 42,999	31	2.8	−0.3	0.0	4.8
REGION (URBAN):					
NEW ENGLAND	136	1.0	−0.1	−0.2	3.0
MIDDLE ATLANTIC	380	−1.7	−0.7	0.0	0.0
SOUTH ATLANTIC	429	0.4	1.3	0.1	4.1
EAST NORTH CENT	444	−0.4	−0.5	0.1	1.5
EAST SOUTH CENT	154	1.3	1.8	0.1	5.5
WEST NORTH CENT	183	−0.1	0.2	0.1	2.5
WEST SOUTH CENT	323	−1.5	1.6	0.0	2.3
MOUNTAIN	129	0.1	1.2	0.0	3.6
PACIFIC	391	−0.2	0.4	0.0	2.5
PUERTO RICO	39	1.2	−5.6	−0.2	−2.3
REGION (RURAL):					
NEW ENGLAND	51	0.4	−2.3	−0.4	0.0
MIDDLE ATLANTIC	72	−0.3	−2.1	0.1	−0.1
SOUTH ATLANTIC	276	1.8	−0.8	−0.1	3.2
EAST NORTH CENT	275	1.5	−2.5	−0.1	1.2
EAST SOUTH CENT	250	1.5	−0.9	−0.1	2.8
WEST NORTH CENT	501	1.3	−2.1	−0.3	1.2
WEST SOUTH CENT	326	1.4	−0.2	−0.2	3.2
MOUNTAIN	200	1.6	−1.1	−0.5	2.4
PACIFIC	137	−0.3	−1.2	−0.2	0.6
PUERTO RICO	5	4.2	−3.1	−0.3	3.0
TEACHING STATUS:					
NON–TEACHING	3,594	0.2	−0.4	0.0	2.1
MINOR	812	0.0	0.6	0.1	3.0
MAJOR	294	−0.7	−0.1	−0.2	1.3
DSH PATIENT PERCENT:					
0	27	0.0	−1.1	−0.7	0.7
GT 0–0.10	1,298	−0.1	−0.3	0.0	2.0
0.10–0.16	1,047	0.2	−0.2	0.1	2.3
0.16–0.23	822	−0.1	0.3	0.0	2.5
0.23–0.35	812	0.1	0.2	0.0	2.6
GE 0.35	695	−0.2	0.1	−0.3	2.0
URBAN IME/DSH:					
IME & DSH	1,012	−0.4	0.5	0.0	2.4
IME/NO DSH	4	−0.1	−2.2	−1.2	−1.0
NO IME/DSH	1,578	−0.2	0.2	0.1	2.4
NO IME/NO DSH	14	0.1	0.9	0.7	4.0

TABLE 6.—IMPACT OF CHANGES FOR CY 2002 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

[Percent changes in total payments (program and beneficiary)]

	Number of hospitals [1] (1)	New wage index [2] (2)	APC recalib.[3] (3)	New outlier policy [4] (4)	All CY 2002 changes [5] (5)
RURAL HOSP. TYPES:					
NO SPECIAL STATUS	797	0.5	−2.0	−0.2	0.6
RRC	171	2.3	−0.5	0.1	4.2
SCH/EACH	656	0.7	−2.2	−0.4	0.5
MDH	327	0.2	−2.5	−0.5	−0.4
SCH AND RRC	70	2.1	−0.9	−0.1	3.4
TYPE OF OWNERSHIP:					
VOLUNTARY	2,808	−0.1	−0.1	0.0	2.2
PROPRIETARY	761	0.0	0.9	0.2	3.4
GOVERNMENT	1,132	0.4	−0.4	−0.2	2.1
SPECIALTY HOSPITALS:					
EYE AND EAR	12	0.1	−8.3	0.6	−5.3
TRAUMA	154	−0.2	−0.1	−0.1	1.9
CANCER	10	−1.7	2.3	−1.6	1.2
TEFRA HOSPITALS (NOT INCLUDED ON OTHER LINES):					
REHAB	164	−1.8	10.0	−1.0	8.9
PSYCH	88	−1.4	−0.6	−3.5	−3.1
LTC	83	−0.7	−2.3	−0.2	−1.0
CHILDREN	41	−0.6	−2.0	−2.2	−2.2

[1] Some data necessary to classify hospitals by category were missing; thus, the total number of hospitals in each category may not equal the national total.

[2] This column shows the impact of updating the wage index used to calculate payment using the proposed FY 2002 hospital inpatient wage index after geographic reclassification by the Medicare Geographic Classification Review Board. The hospital inpatient proposed rule for FY 2002 was published in the **Federal Register** on May 4, 2001.

[3] This column shows the impact of recalibrating the APC weights based on 1999–2000 hospital claims data and of the reassignment of some HCPCs to APCs as discussed in this rule.

[4] This column shows the difference in calculating outliers on an APC-specific rather than bill basis.

[5] This column shows changes in total payment from CY 2001 to CY 2002. It incorporates all of the changes reflected in columns 2, 3, and 4. In addition, it shows the impact of the CY 2002 payment update. The sum of the columns may be different from the percentage changes shown here due to rounding.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

A. Part 413 is amended as set forth below:

1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395g, 1395l, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

Subpart B—Accounting Records and Reports

2. In § 413.24, the heading to paragraph (d) is republished, paragraph (d)(6) is revised, and a new paragraph (d)(7) is added, to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(d) *Cost finding methods.* * * *

(6) *Provider-based entities and departments: Preventing duplication of cost.* In some situations, the main provider in a provider-based complex may purchase services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the main provider cannot be separately identified, the costs of the services purchased through a contract

must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

Example: A provider-based complex is composed of a hospital and a hospital-based rural health clinic (RHC). The hospital furnishes the entirety of its own administrative and general costs internally. The RHC, however, is managed by an independent contractor through a management contract. The management contract provides a full array of administrative and general services, with the exception of patient billing. The hospital directly assigns the costs of the RHC's management contract to the RHC cost center (for example, Form HCFA 2552–96, Worksheet A, Line 71). A full allocation of the hospital's administrative and general costs to the RHC cost center would duplicate most of the RHC's administrative and general costs. However, an allocation of the hospital's cost (included in hospital administrative and general costs) of its patient billing function to the RHC would be appropriate. Therefore, the hospital must include the costs of the patient billing function in a separate cost center to be allocated to the benefiting cost centers, including the RHC cost center. The remaining hospital administrative and general costs would be allocated to all cost centers, excluding the RHC cost center. If the hospital is unable to isolate the costs of the patient billing function, the costs of the RHC's management contract must be reclassified to the hospital administrative and general cost center to be allocated among all cost centers, as appropriate.

(7) *Costs of services furnished to free-standing entities.* The costs that a provider incurs to furnish services to free-standing entities with which it is associated are not allowable costs of that provider. Any costs of services furnished to a free-standing entity must be identified and eliminated from the allowable costs of the servicing provider, to prevent Medicare payment to that provider for those costs. This may be done by including the free-standing entity on the cost report as a nonreimbursable cost center for the purpose of allocating overhead costs to that entity. If this method would not result in an accurate allocation of costs to the entity, the provider must develop detailed work papers showing how the cost of services furnished by the provider to the entity were determined. These costs are removed from the applicable cost centers of the servicing provider.

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Subpart E—Payments to Providers

3. Section 413.65 is amended as follows:

A. Revising paragraph (a)(1).

B. Revising the definition of ''Provider-based entity'' in paragraph (a)(2).

C. Revising paragraph (b).

D. Revising paragraph (c).

E. Revising the introductory text to paragraph (d).

F. Revising paragraph (d)(7).

G. Revising paragraph (g)(7).

H. Revising the introductory text to paragraph (i)(1).

I. Revising paragraph (i)(1)(ii).

J. Revising paragraph (i)(2).

The revisions read as follows:

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions.* (1) *Scope.* (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in § 412.22(h)(1) and § 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

(ii) This section does not apply to the following facilities:

(A) Ambulatory surgical centers (ASCs).

(B) Comprehensive outpatient rehabilitation facilities (CORFs).

(C) Home health agencies (HHAs).

(D) Skilled nursing facilities (SNFs).

(E) Hospices.

(F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.

(G) Independent diagnostic testing facilities and any other facilities that furnish only clinical diagnostic laboratory tests.

(H) Facilities furnishing only physical, occupational, or speech therapy to ambulatory patients, for as long as the $1,500 annual cap on coverage of physical, occupational, and speech therapy, as described in section 1833(g)(2) of the Act, remains suspended by the action of subsequent legislation.

(I) ESRD facilities (determinations for ESRD facilities are made under § 413.174 of this chapter).

(2) *Definitions.* * * *

* * * * *

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the name, ownership, and administrative and financial control of the main provider, in accordance with the provisions of this section.

* * * * *

(b) *Provider-based determinations.* (1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until October 1, 2002, and the requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), and (h) of this section will not apply to that hospital or CAH for that facility until October 1, 2002. For purposes of this paragraph, a facility will be considered to have been treated as provider-based on October 1, 2000, if on that date it either had a written determination from CMS that it was provider-based as of that date, or was billing and being paid as a provider-based department or entity of the hospital.

(3) Except as specified in paragraphs (b)(2) and (b)(5) of this section, a main provider or a facility must contact CMS, and the facility must be determined by CMS to be provider-based, before the main provider bills for services of the facility as if the facility were provider-based, or before it includes costs of those services on its cost report.

(4) A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in physician offices are furnished is presumed to be a free-standing facility, unless it is determined by CMS to have provider-based status.

(5) A facility for which a determination of provider-based status in relation to a hospital or CAH is requested on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.

(c) *Reporting.* A main provider that has had one or more facilities considered provider-based also must report to CMS any material change in the relationship between it and any

provider-based facility, such as a change in ownership of the facility or entry into a new or different management contract that could affect the provider-based status of the facility.

(d) *Requirements.* An entity must meet all of the following requirements to be determined by CMS to have provider-based status.

* * * * *

(7) *Location in immediate vicinity.* The facility or organization and the main provider are located on the same campus, except when the requirements in paragraphs (d)(7)(i), (d)(7)(ii), or (d)(7)(iii) of this section are met:

(i) The facility or organization is located within a 35-mile radius of the main campus of the hospital or CAH that is the potential main provider;

(ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services to low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or

(C) If the facility or organization is unable to meet the criteria in paragraph (d)(7)(i)(A) or (d)(7)(i)(B) of this section because it was not in operation during all of the 12-month period described in the previous sentence, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in the previous sentence, accounted for at least 75 percent of the patients served by the main provider.

(iv) A facility or organization is not considered to be in the ''immediate vicinity'' of the main provider unless the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, adjacent States.

(v) An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in § 412.62(f)(1)(iii) of this chapter, and has fewer than 50 beds, as determined under § 412.105(b) of this chapter, is not subject to the criteria in paragraphs (d)(7)(i) through (d)(7)(iv) of this section.

* * * * *

(g) *Obligations of hospital outpatient departments and hospital-based entities.* * * *

* * * * *

(7) When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, the hospital has a duty to provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, of the fact that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability). The notice must be one that the beneficiary can read and understand. If the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains the fact that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based. The hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital. If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

* * * * *

(i) *Inappropriate treatment of a facility or organization as provider-based.* (1) *Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider had not obtained a determination of provider-based status under this section, CMS will—

* * * * *

(ii) Investigate and determine whether the requirements in paragraph (d) of this section (or, for periods before the beginning of the hospital's first cost reporting period beginning or or after January 10, 2001, the requirements in applicable program instructions) were met; and

* * * * *

(2) *Recovery of overpayments.* If CMS finds that payments for services at the facility or organization have been made as if the facility or organization were provider-based, even though CMS had not previously determined that the facility or organization qualified for provider-based status, CMS will recover the difference between the amount of payments that actually were made and the amount of payments that CMS estimates should have been made in the absence of a determination of provider-based status, except that recovery will not be made for any period before the beginning of the hospital's first cost reporting period beginning or or after January 10, 2001 if during all of that period the management of the entity made a good faith effort to operate it as a provider-based facility or organization, as described in paragraph (h)(3) of this section.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

B. Part 419 is amended as set forth below:

1. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

Subpart A—General Provisions

2. In § 419.2, paragraph (c) is revised to read as follows:

§ 419.2 Basis of payment.

* * * * *

(c) *Determination of hospital outpatient prospective payment rates: Excluded costs.* The following costs are excluded from the hospital outpatient prospective payment system.

(1) The costs of direct graduate medical education activities as described in § 413.86 of this chapter.

(2) The costs of nursing and allied health programs as described in § 413.85 of this chapter.

(3) The costs associated with interns and residents not in approved teaching programs as described in § 415.202 of this chapter.

(4) The costs of teaching physicians attributable to Part B services for hospitals that elect cost-based reimbursement for teaching physicians under § 415.160.

(5) The reasonable costs of anesthesia services furnished to hospital outpatients by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologists' assistants) employed by the hospital or obtained under arrangements, for hospitals that meet the requirements under § 412.113(c) of this chapter.

(6) Bad debts for uncollectible deductibles and coinsurances as described in § 413.80(b) of this chapter.

(7) Organ acquisition costs paid under Part B.

(8) Corneal tissue acquisition costs.

Subpart B—Categories of Hospitals and Services Subject to and Excluded From the Hospital Outpatient Prospective Payment System

3. In § 419.20, paragraph (a) is revised, and paragraphs (b)(3) and (b)(4) are added to read as follows:

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

(a) *Applicability.* The hospital outpatient prospective payment system is applicable to any hospital participating in the Medicare program, except those specified in paragraph (b) of this section, for services furnished on or after August 1, 2000.

(b) *Hospitals excluded from the outpatient prospective payment system.*

* * * * *

(3) A hospital located outside one of the 50 States, the District of Columbia, and Puerto Rico is excluded from the hospital outpatient prospective payment system.

(4) A hospital of the Indian Health Service.

4. In § 419.22, the introductory text is republished, and paragraph (r) is added to read as follows:

§ 419.22 Hospital outpatient services excluded from payment under the hospital outpatient prospective payment system.

The following services are not paid for under the hospital outpatient prospective payment system:

* * * * *

(r) Services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.

Subpart C—Basic Methodology for Determining Prospective Payment Rates for Hospital Outpatient Services

5. In § 419.32, paragraph (b)(1) is revised to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) *Conversion factor for calendar year 2000 and subsequent years.* (1) Subject to paragraph (b)(2) of this section, the conversion factor for a calendar year is equal to the conversion factor calculated for the previous year adjusted as follows:

(i) For calendar year 2000, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point.

(ii) For calendar year 2001—

(A) For services furnished on or after January 1, 2001 and before April 1, 2001, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point; and

(B) For services furnished on or after April 1, 2001 and before January 1, 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, and increased by a transitional percentage allowance equal to 0.32 percent.

(iii) For calendar year 2002, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act reduced by one percentage point, without taking into account the transitional percentage allowance referenced in § 419.32(b)(ii)(B).

(iv) For calendar year 2003 and subsequent years, by the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

* * * * *

Subpart D—Payments to Hospitals

6. In § 419.40, the word ''coinsurance'' is removed and the word ''copayment'' is added in its place as follows:

§ 419.40 Payment concepts.

(a) In addition to the payment rate described in § 419.32, for each APC group there is a predetermined beneficiary copayment amount as described in § 419.41(a). The Medicare program payment amount for each APC group is calculated by applying the program payment percentage as described in § 419.41(b).

(b) For purposes of this section—

(1) Coinsurance percentage is calculated as the difference between the program payment percentage and 100 percent. The coinsurance percentage in any year is thus defined for each APC group as the greater of the following: the ratio of the APC group unadjusted copayment amount to the annual APC group payment rate, or 20 percent.

(2) Program payment percentage is calculated as the lower of the following: the ratio of the APC group payment rate minus the APC group unadjusted copayment amount, to the APC group payment rate, or 80 percent.

(3) Unadjusted copayment amount is calculated as 20 percent of the wage-adjusted national median of charges for services within an APC group furnished during 1996, updated to 1999 using an actuarial projection of charge increases for hospital outpatient department services during the period 1996 to 1999.

(c) *Limitation of copayment amount to inpatient hospital deductible amount.* The copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year.

7. Amend § 419.41 as follows:

A. The section heading is revised.

B. The word ''coinsurance'' is removed each time it appears, and the word ''copayment'' is added in its place.

C. Paragraph (c)(4)(ii) is redesignated as paragraph (c)(4)(iv).

D. Paragraphs (c)(4)(ii) and (c)(4)(iii) are added as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

(c) * * *

(4) * * *

(i) Effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective payment rate for that APC.

(ii) The national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar years

2002 and 2003; 50 percent in calendar year 2004; 45 percent in calendar year 2005; and 40 percent in calendar year 2006 and thereafter.

* * * * *

8. In § 419.42 paragraph (a), (c), and (e) are revised as follows:

§ 419.42 Hospital election to reduce coinsurance.

(a) A hospital may elect to reduce coinsurance for any or all APC groups on a calendar year basis. A hospital may not elect to reduce copayment amounts for some, but not all, services within the same group.

* * * * *

(c) The hospital's election must be properly documented. It must specifically identify the APCs to which it applies and the copayment amount (within the limits identified below) that the hospital has selected for each group.

* * * * *

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined in § 419.32.

* * * * *

§ 419.43 [Amended]

9. Section 419.43 is amended by removing the word ''coinsurance'' from the section heading and from paragraph (a), and adding the word ''copayment'' in its place.

Subpart G—Transitional Corridors

10. In § 419.70, paragraph (d)(2) is revised to read as follows:

§ 419.70 Transitional adjustment to limit decline in payment.

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(d) *Hold harmless provisions* * * *

* * * * *

(2) *Permanent treatment for cancer hospitals and children's hospitals.* In the case of a hospital described in § 412.23(d) or § 412.23(f) of this chapter for which the prospective payment system amount is less than the pre-BBA amount for covered hospital outpatient services, the amount of payment under this part is increased by the amount of this difference.

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PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

C. Part 489 is amended as set forth below:

1. The authority citation to part 489 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Essentials of Provider Agreements

2. In § 489.24, paragraph (i)(2)(ii) is revised to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

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(i) *Off-campus departments.* * * *

(2) *Protocols for off-campus departments.* * * *

* * * * *

(ii) If the off-campus department is a physical therapy, radiology, or other facility not routinely staffed with physicians, RNs, or LPNs, the department's personnel must be given protocols that direct them to contact emergency personnel at the main hospital campus for direction. Under this direction, and in accordance with protocols established in advance by the hospital, the personnel at the off-campus department must describe patient appearance and report symptoms and, if appropriate, either arrange transportation of the individual to the main hospital campus in accordance with paragraph (i)(3)(i) of this section or assist in an appropriate transfer as described in paragraphs (i)(3)(ii) and (d)(2) of this section. Any contact with emergency personnel at the main hospital campus should either be made after or concurrently with the actions needed to arrange an appropriate transfer under paragraph (i)(3)(ii) of this section if doing otherwise would significantly jeopardize the life or health of the individual.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 3, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 3, 2001.

Tommy G. Thompson,

Secretary.

ADDENDUM A.—LIST OF AMBULATORY PAYMENT CLASSIFICATIONS (APCS) WITH STATUS INDICATORS, RELATIVE WEIGHTS, PAYMENT RATES, AND COPAYMENT AMOUNTS CALENDAR YEAR 2002

APC	Group Title	Status Indicator	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0001	Photochemotherapy	S	0.45	$22.88	$8.24	$4.58
0002	Fine needle Biopsy/Aspiration	T	0.47	$23.90	$13.14	$4.78
0003	Bone Marrow Biopsy/Aspiration	T	1.11	$56.43	$27.99	$11.29
0004	Level I Needle Biopsy/ Aspiration Except Bone Marrow	T	3.00	$152.53	$32.57	$30.51
0005	Level II Needle Biopsy /Aspiration Except Bone Marrow	T	6.71	$341.15	$119.75	$68.23
0006	Level I Incision & Drainage	T	2.36	$119.99	$33.95	$24.00
0007	Level II Incision & Drainage	T	7.28	$370.13	$74.03	$74.03
0008	Level III Incision and Drainage	T	11.36	$577.57	$115.51	$115.51
0009	Nail Procedures	T	0.68	$34.57	$8.99	$6.91
0010	Level I Destruction of Lesion	T	0.71	$36.10	$9.86	$7.22
0011	Level II Destruction of Lesion	T	1.57	$79.82	$29.53	$15.96
0012	Level I Debridement & Destruction	T	0.72	$36.61	$9.18	$7.32
0013	Level II Debridement & Destruction	T	1.51	$76.77	$17.66	$15.35
0015	Level IV Debridement & Destruction	T	2.29	$116.43	$31.20	$23.29
0016	Level V Debridement & Destruction	T	3.31	$168.29	$70.68	$33.66
0017	Level VI Debridement & Destruction	T	10.51	$534.35	$245.80	$106.87
0018	Biopsy of Skin/Puncture of Lesion	T	1.16	$58.98	$17.66	$11.80
0019	Level I Excision/ Biopsy	T	4.56	$231.84	$78.91	$46.37
0020	Level II Excision/ Biopsy	T	8.56	$435.21	$130.53	$87.04
0021	Level IV Excision/ Biopsy	T	12.74	$647.73	$236.51	$129.55
0022	Level V Excision/ Biopsy	T	15.07	$766.19	$292.94	$153.24
0023	Exploration Penetrating Wound	T	2.18	$110.84	$40.37	$22.17
0024	Level I Skin Repair	T	2.48	$126.09	$44.50	$25.22
0025	Level II Skin Repair	T	3.71	$188.62	$70.66	$37.72